

בעזרת השם יתברך

ספר
שלום שלום לרחוק
ולקרוב ורפאתיו

בירור הלכה המבארת
יצירת התרופות הרפואיות,
וכשרותם לכל השנה (בכלל)
ולחג הפסח (בפרט), באנגלית.



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PART 2

MEDICINE AND PASSOVER LAW

Halachic clarification explaining the production of medicines, and their kashrus for the whole year (in general) and (especially) for Passover, based on a detailed study of the pharmacologic production process.

**Laws of medicines
Question**

Kislev 10, 5737

Dear Rabbi..., author of ...

I appeal to you to instruct me in the pleasant ways of the word of Hashem, which is the halacha. Please do not be angry with me for troubling you with my letter...I trust that you will not disregard my request, but will answer me as soon as possible.

I wish to know if and how it is possible for organizations or private rabbis to make *lists* and to discuss the kashrus of various medicines for the entire year in general and especially for Passover.

Because of the difficulties involved in arranging *hashgachah* in factories and in clarifying by chemical tests which medicines are kosher and which are not, we are compelled to send requests to various medical authorities—government bureaus, pharmaceutical companies, organizations of pharmacists and physicians, outstanding physicians, chemists, and pharmacists—to seek their assistance in this matter. I emphasize that there was no visit to any factory ... everything is based on written replies.

I have come to ask: May we rely on these responses even to *permit* certain pharmaceuticals? Or only negatively, i.e. if they write that the pharmaceuticals contain non-kosher ingredients? Second, is it permissible or *proper* to publicize the contents of these letter in a manner that the public will rely on them?

As we step from the sanctuary, let my lips utter a prayer to He Who dwells on high, to grant you longevity and strength to be able to enjoy the presence of Hashem in His pure service, in good health and tranquility, until we will be redeemed forever by welcoming the *Messiah*, with the leaders of our generation at our head, speedily in our days, amen.

Respectfully,

Rabbi....

Responsum

Honorable and esteemed Rabbi.....

If all the seas were ink, the reeds pens, the skies parchment, and all people scribes, they would not be able to record the devices of political government (*Shabbos 11*). i.e. it is very difficult to write all the matters with which the government must concern itself. As it is said: (*Prov. 25:3*) *The heavens for height, and the earth for depth, and the heart of kings is unsearchable.* Meiri explains: The government is burdened with so many obligations, which the average person would find difficult to evaluate.

In writing this chapter concerning pharmaceuticals, I communicated with the managers of all the major pharmaceutical firms in the United States to receive thorough information pertaining to the manufacture of pharmaceuticals and related matters, and their bearing on the *kashrus* of products. The most important thing I learned from all of them is that it is *impossible* to know definitely the contents of any given pharmaceutical for any length of time—and sometimes even for a short time—since the manufacturing process and the ingredient origin change from day to day. Moreover, they may be produced differently in different parts of our country. Hence, it must be determined—whether it was produced in the East, West, North, or South.

My study in this matter was based on the question regarding the presence of various animal and grain derivatives in drug products for purposes of determining whether these conform with Jewish Dietary Laws.

I queried those knowledgeable and explained to them briefly all the halachos and ramifications of the laws of *kashrus*.

You should know that every rabbi who is well-versed in these matters must differentiate between two kinds of medicines:

- 1) Prescription drugs.
- 2) Over-the-counter drugs.

Without a doubt, over-the-counter drugs cannot be permitted if they contain any non-kosher ingredient, since there is always an alternative.

According to government figures, there are 350,000 such medicines in the United States.

As regards prescription drugs, the following questions must be considered:

- 1) Whether the patient's life is in danger.
- 2) Whether there is an alternative, i.e. whether another medicine can be substituted for the prescribed medicine containing the non-kosher ingredient.

It is important to emphasize that there is no question concerning medicinals which are critical to the health of an individual or to indications which are serious in nature.

I

CONSTANT REFORMULATION

First, the production methodology of every medicine changes periodically.

We quote below statements made by the world's largest companies.

ABBOT PHARMACEUTICAL PRODUCTS DIVISION ABBOT LABORATORIES

...regarding specific ingredients in specific products. I am sure you are aware of the great amount of time required to check the formula of all the Abbot products to see if they contain... (prohibited substances). Not only would the final formula have to be checked, but the formula for many of the ingredients (also) to see if they contained these prohibited substances.

We prefer that such lists not be made due to the frequency with which our products formulas change. At any time a

product may be reformulated and have the prohibited substance removed. More importantly, a product not on the list could have the prohibited ingredient added.

General or specific statements cannot be made for so many varied products.

2. PARKE, DAVIS & COMPANY:

Parke-Davis has several hundred products which might be used in treatment. I hope you will understand that *it is impossible for us to give you a complete breakdown of all components and also that they may be subject to revision from time to time because of various reasons.*

3. SYNTEX RESEARCH

DIVISION OF SYNTEX (U.S.A.) INC.

INSTITUTE OF PHARMACEUTICAL SCIENCES:

Many components are used in compounding pharmaceutical formulations. These materials might be animal, vegetable, and/or mineral in origin. Many of these ingredients are produced by reactions of other chemical materials, and so attempting to learn whether any animal materials were used in the manufacture of a product becomes *a complex maze*. It would require a skilled detective to unravel some of the intricacies of the reactants which are utilized, and I think that answer might often depend more on zeal, orthodoxy, and Talmudic interpretation than on mere catalogue listings.

In regard to grain products, in tableting we also employ such materials as wheat starch and corn starch. I *question whether you could obtain more than a few tablets on the market which did not contain some corn starch*. Wheat starch is much less commonly used. Furthermore, any products which contain alcohol such as elixirs and some cough syrups would contain grain alcohol.

4. CIBA — GEIGY CORPORATION PHARMACEUTICALS DIVISION

An effort to determine which of our products are kosher and which are not would be a monumental task. In addition, I doubt *whether any company has products which would be considered as kosher unless it had made a concerted effort to manufacture them.*

5. SYNTEX RESEARCH DIVISION OF SYNTEX (U.S.A.) INC.

I consider the impossibility of tracing the origin and genealogy of materials such as surface active agents, fats and alcohols. To further compound the problem, the same chemicals purchased from different manufacturers can be made by many different processes and may have utilized many different intermediates. You have a scientific recognition of the *enormity of the problem of ever being able to say that a particular chemical of commerce did or did not comply with the standards of kashruth...*

...there is no way in which we can determine the sources of origin of these materials or how they were prepared. Neither could we guarantee that the materials will be purchased each time from the same manufacturer.

II

PURITY OF MATERIALS TO MEET GOVERNMENT STANDARDS

The companies explain that they are responsible to observe the purity of the materials and the pharmaceuticals *only insofar as is required by government regulations.*

They all have to meet the highest compendial standards of purity. In their words, their products are produced according to "United States Pharmacopeia or National Formulary".

This, however, deals exclusively with purity from foreign matter, which can harm the chemical material (such as

bacteria)—but not concerning its origin, as indicated by the following.

1. CIBA - GEIGY CORPORATION PHARMACEUTICALS DIVISION

I can tell you that as a *general rule the majority of tablets and capsules contain either magnesium or calcium stearate*. The source of this stearate can be either animal or vegetable fat, but *no major pharmaceutical company, to the best of my knowledge, make a conscious attempt to control the material which they receive to one type or the other*. The criteria for acceptance or rejection is based on the stearates meeting company specifications usually related to the United States Pharmacopoeia or National Formulary.

[They state also that the government is not particular concerning the origin of the ingredients used in pharmaceuticals.]

2. CHESEBROUGH—PONDS INC

All ingredients used in our products meet fully the standards and specifications that have been established *in the official compendia* or that are recognized as assuring their quality, strength and purity. I am sure that you understand that *these standards are not specific in regard to the sources of certain ingredients*. For example, ethyl alcohol can be derived from starches (wheat, corn or potato), sugars (cane or beet) or prepared synthetically. Similarly, glycerin can be derived from vegetable oils animal fats or prepared synthetically. Furthermore, certain processes used to prepare ingredients from their source materials are essentially chemical syntheses that result in a new chemical entity. *Our purchasing specifications do not generally require that such ingredients be from a particular source or derived by a particular process*.

III

HALACHIC RELIABILITY OF RESPONSES

Even after a company answers with certainty that a certain pharmaceutical contains no *non-kosher* ingredient, since they knew definitely at the time of their answer why we asked them, there is a halachic question as to whether they can be relied upon under the “conversing innocently” *מסיח לפי תדמיו* principle.

The basis of “conversing innocently” of the letters of the managers of the companies, upon which we build lofty edifices, is faulty. For example, we wrote to a company a letter worded clearly and simply. Nevertheless, their reply was:

SANDOZ PHARMACEUTICALS

...we are returning the completed schedule for “Ingredient Identification”

...dilutant: lactose

...lubricant: stearic acid, calcium stearate

Notes:

a) lactose is a sugar derived from milk; it is questionable as to whether it is actually a milk by-product.

b) stearic acid and calcium stearate are tallow derivatives, usually obtained from cattle and sheep. There are refined to the extent that “meat” is not present.

[Apparently, even though we wrote clearly, they replied according to their comprehension of the matter. They understand that if there is no meat contained in the product, it is not considered a meat product.]

IV MACHINERY

We learned from their responses below that there is another question involved in the production of the pharmaceuticals: their *machinery*.

1. STUART PHARMACEUTICALS, DIVISION OF ICI AMERICA, INC

“Acceptability” from a kosher standpoint is based on the nature of the *ingredients*. It must be recognized that the *equipment* used by the *manufacturer* of the raw materials employed in these products or by Stuart Pharmaceuticals in manufacturing these products, even though thoroughly cleaned, *may not qualify* as Kosher because of *previous contact with non-Kosher products*.

“Acceptability” for Passover is based on the nature of the *ingredients*. The possibilities exist that the *equipment* used by the *manufacturer* of the raw materials or by Stuart Pharmaceuticals in manufacturing these products, even though thoroughly cleaned, may have been in previous contact with other products containing grain-derived materials.

[This means:

- 1) They purchase ingredients from other companies. They do not know their nature or the process of their production: they may, therefore, contain non-kosher ingredients.
- 2) Even if they are free of non-kosher ingredients, they were manufactured with machines used previously for non-kosher materials.
- 3) This problem involves both the company that **finishes** the pharmaceutical and the company that prepared the various ingredients and sells them to others to produce from them whatever they wish.]

2. ABBOTT PHARMACEUTICAL PRODUCTS DIVISION

...concerning ingredients used in various medicinal products. We have several hundred formulas and we are not in a position to go through them in detail to determine all of the ingredients used in them.

It is true that we use animal products such as gelatin in many of our products. In additions, stearates, which are usually derived from the animal fat, are frequently used. Lactose from milk, corn starch and alcohol from grain and many other agents are used. *Frequently we are purchasing these items from outside vendors and do not know the originating source of many of these items. Sometimes the products can be derived from natural sources or synthesized. We make no distinction in purchasing between these two sources and do not have available to us the information you request.*

3. CHESEBROUGH—PONDS INC

In regard to manufacturing and processing equipment, we use separate equipment for each product, except in a few cases where products are essentially similar composition. All equipment is routinely cleaned and sanitized *in accordance with currently accepted good manufacturing practices for drug products.*

[The cleaning of utensils and caring for their cleanliness are done only as far as compliance with government standards requires. Such cleaning does not comply with standards demanded by the holy Torah.]

V

INGREDIENTS OF CAPSULES AND TABLETS

**STUART PHARMACEUTICALS
DIVISION OF ICI AMERICA INC**

...regarding a "capsule" and the possible freedom of our capsulated products from any animal derivatives. Since *almost all of the capsulated products* manufactured in this country contain *gelatin* as the capsulating material, it is apparent that *none of these products (either ours or those of other manufacturers) are free of animal (mammalian) derivatives.* Indeed, we are not aware of a source of capsules *where the gelatin is derived from kosher sources, e.g., kosher-killed animals or fish.*

[That means that they are all produced from non-kosher ingredients! They wrote too that tablets are included, as below.]

2. SQUIBB

Small amounts of stearic acid or magnesium stearate *are used in most capsule and tablet formulations.* In *nearly all cases,* it would be derived from *animal sources.*

3. MILES LABORATORIES, INC.

Small amounts of animal-derived substances (magnesium stearate and gelatin) are employed in many tableted products as lubricants and binders.

4. A.H. ROBINS COMPANY

...*alcohol* could either be synthetic or might be derived from grain.

...*glucose* is derived from starch which might be derived from grain.

...*glycerin* could *at any one time* be from animal, vegetable or synthetic sources and it would be *impossible* to state that the animal source was *not porcine.*

...*Lactose* is milk sugar.

...*magnesium stearate* is synthesized from stearic acid which is derived from animal fats.

5. BOEHAINGER INGELHEIM

Gelatin—derived from the skin, white connective tissue and bones of animals.

Stearic Acid—derived from the fat of cattle and sheep.

6. STUART PHARMACEUTICAL PRODUCTS

- *Magnesium stearate* (source of stearic acid while known to be of vegetable origin is unknown as regards grain or acceptable seeds, (e.g. cottonseed or peanuts).

psyllium is derived from psyllium which is not considered to be a grain.

flavors dissolved in ethyl alcohol; *source unknown*.

vegetable-oil derived *stearates* of *unknown* origin.

VI

THE QUANTITY OF NON-KOSHER INGREDIENTS IN PHARMACEUTICALS

The solution of the question of the *quantity* of non-kosher ingredients in the entire pharmaceutical, in order to determine whether it can be annulled by sixty times as much kosher material, is also not simple.

1. STUART PHARMACEUTICALS DIVISION OF ICI AMERICA INC.

The question as to whether the percentage of gelatin is less than 1.5% of the *gross weight* of the tablet or of the *volume* of the tablet appears to be moot, since it has been my assumption that it is not the concentration of gelatin which is important, but rather the source. The gelatin in our products is from animal (mammalian) sources and is non-kosher.

VII MEAT AND MILK

A question came up regarding the mixture of milk and meat... in addition to the prohibition of *cholov akkum*, which most *poskim* prohibit (See *Nefesh Yeshayah* and *Minchas Yehuda*). Even according to some rabbis who permit unsupervised milk, our original question is whether this medicine derived from milk may be eaten with food containing meat or after food containing meat. It is interesting that one company understood this question by themselves and wrote to us as follows:

1. CIBA — GEIGY CORPORATION PHARMACEUTICALS DIVISION

My rabbi has informed me that today the majority of animals are slaughtered under kosher conditions. However, we cannot be a hundred percent certain about our material. In addition, most tablets and capsules also contain lactose as an excipient. Lactose, being milk sugar, would represent a dairy item and if combined with magnesium or calcium stearate from animal sources would be comparable to mixing dairy and meat products together. [They add that the order for Kosher tablets and capsules is hard to fill].

Thus the only way you could be certain of obtaining tablets and capsules which would meet with the laws of "kashrus" would be for a company to make a concerted effort to use only stearates manufactured from vegetable sources, or to use only stearates obtained from animals which have been killed under kosher conditions, and at the same time exclude the use of milk sugar as one of the dosage from excipients, or as a special research project, to develop a series of new (possibly inorganic) excipients which would fall into a neutral area and be excluded from the laws of "Kashrus."

We obtain our stearates from a number of suppliers, some of whom tell us they are supplying material from animal fat, others from vegetable oils. Therefore lots of our products may be made with purely vegetable material, other lots with animal fats. *Furthermore, even if we controlled certain products putting into them only the vegetable fat, they would be manufactured on the same equipment which is used to manufacture that containing animal fats.* In my opinion this would be comparable to someone who keeps a kosher home and then intermixes the dairy and meat cooking utensils...

He concludes:

Although I am presently a member of a reform congregation, I came from an orthodox family who attended an orthodox synagogue. It was always my understanding that the laws of the "Kashrus" were waved in cases which involved the health of the individual. I have recently discussed this matter with my, as well as other, rabbis and have been informed that the Torah does state this in regard to the health of the individual. I was wondering if there is a newer interpretation and therefore the concept of health coming before "Kashrus" is no longer considered to be valid.

VIII SUMMARY

To sum up our observations we can state definitely that it is impossible for the company that manufactures a pharmaceutical, to know the *content* and the nature of *all* its various ingredients.

A summary of all the letters can be found in the letter below, which explains that all pharmaceutical companies state unanimously that they all follow the same practices, and their statements coincide with one another.

1. BRISTOL LABORATORIES BRISTOL—MYERS COMPANY

...Information on the source of materials used in various types of medications:

In *general*, I think you will find that *most* pharmaceutical manufacturers tend to use the same general types of ingredients in similar product groupings.

One notable exception is the fact that sucrose, which is used in relatively high concentrations in syrups and powders for reconstitution with water, is primarily derived from sugar cane if the material is used in the East and South, and from beets if the sucrose is used in the Midwest or West. In our case, all of our sucrose is obtained from cane. In general, the flavors and colors used in syrups and tablets are of artificial origin.

Lactose is *commonly* used in tablets and capsules as a filler. This material, of course, is derived from milk. *Most* tablets also contain corn starch. *Capsules, of course, are made of gelatin, which is of animal origin.*

The other materials you mentioned in your letter, such as buffers and preservatives, are *generally* produced by chemical synthesis.

I hope that the above information, although necessarily *general* in nature, will be of some help to you.

[The word, "general" means that the product is made in a certain manner as a rule, but there is no assurance by the manufacturer that it is always produced in this manner. How, then, can we rely on such a thing?]

IX

PRACTICAL APPLICATION OF OUR FINDINGS

It is a great responsibility to make a list of *kosher* pharmaceuticals for the entire year and for Passover, since the

methods of production change periodically *as well as the ingredients*. Moreover, it is difficult to formulate a special list for Passover since it must be written several months before the festival, and in the interim, changes may be made in any pharmaceutical. Furthermore, many pharmaceuticals lie in the drug store a long time and it is impossible to determine from which “kettle” the ingredients of any given medicine were made.

We can only rely on the rabbi who decides the *halachah* to answer the one who asks the question; the rabbi will weigh the question in his mind according to the seriousness of the patient’s condition, without relying at all on the knowledge of the production of the medicine, for that is impossible to determine, as delineated above. Each individual’s case is different. It is, therefore, understood that it is *impossible* to make a public announcement or to print any list, either general or special, to allow the general populace to take pharmaceuticals for cures or preservation of health.

The companies are unaware of the change of the source of the ingredients they use in the production of medicines. It is impossible to say that we will be concerned with change only when we discover the change, since it is possible that the change took place some time ago, or recently, or even immediately after the last correspondence, in which they testified that their product is kosher, since changes take place every day. It is halachically unsound to argue that the change took place during the last twenty-four hour period *preceding* the writing of the last letter, which stated that the product is non-kosher, and if there was an earlier letter within that period, to judge that it was kosher until then, since the industry itself testifies that it cannot ascertain whence the ingredients emanate, and into which machine they go.

Our Rabbis stated (*Shabbos* 10) that every judge who renders a true judgment, is considered as though he were a partner with the Holy One, Blessed be He, in the Creation. *Nesivos Olam* explains: The emphasis is that not only must the verdict be true

in view of the claims of the litigants and according to the conclusion of the halachah, but the judge must be certain that the practice that he is following is proper!

The Rabbis, therefore, state often: "This is the halachah, but we should not instruct the public that way." i.e. there are some permissible things that a *talmid chochom* who knows of their permissibility, may practice. The permissibility may not be publicized, however, since it may cause pitfalls for the public.

I pray to the Lord, Who heals all flesh, to send a speedy and complete recovery to all our sick brethren, and may His promise of "Any malady with which I afflicted the Egyptians, I will not visit upon you, for I am the Lord your healer" come to fruition in our days."

May all harsh decrees decreed upon us, be repealed, and may we be blessed with joy and happiness, salvation and consolation, sustenance and nourishment, for good life and peace, and for a quick redemption.

Amen.

With blessings for a kosher and joyous Passover,

—Rabbi Sholom Yehudah Gross

Below is a copy of a portion of the questionnaire I used in the clarification of the manufacture of pharmaceuticals. The reader will see that we have worked in a remarkable way and have confined the main laws related to kashrus in the following pages. When this questionnaire passed under the scrutiny of numerous halachah authorities, they all agreed that the Almighty had prospered our undertaking. The questionnaire itself is rather extensive and long. It was compiled by one of our colleagues, an accomplished halachah authority, a G-d-fearing man, with a knowledge of science. He compiled it in such a way that the respondent would find no misleading questions and would be able to answer correctly concerning every detail of the production of pharmaceuticals, from the formation of the

ingredients until the packing for sale, thus including the entire manufacture (even though it is very detailed), and every ingredient that has a particular purpose, e.g.

Disintegrator, emulsifier, binder, flavoring, dispersing agent, buffer substance, preservative, coloring dilutant, coating, filler, lubricant.... and many more, too numerous to list.

BASIC LAWS OF KASHRUS

KOSHER denotes that which is usable, suited for use or permitted as food pursuant to the Jewish Dietary laws. The antonym is treife. Food, as well as medicinal products require kashrus supervision.

Briefly stated the policy and obligations of food processors vis-a-vis kosher production, are as follows:

1. DEFINITION AND PROCEDURE

In general, products are eligible for *Kosher* certification if they meet the following criteria:

1. Active and inert ingredients are:

- (a) free of:
 - (i) meat, meat fat or meat by products of animal, fowl, mammal, reptile, amphibians, insects or worms, and fish not bearing scales, or their derivatives.
 - (ii) milk, milk by-products or derivatives
 - (iii) wine, wine by-products or derivatives
- (b) processed in equipment which has *not* processed the above enumerated meat, meat fat, meat by-products or derivatives, milk, milk by-products or derivatives, fish not bearing scales, or wine, wine by-products or derivatives.
- (c) free of any *ingredient* which fails to comply with (a) or (b) above.

Examples of non-kosher foods are: *ova* eggs, gelatin, shellfish, cognac, brandy, bread baked in pans greased in fat.

2. Meat or meat by-products, as well as milk and milk by-products are *kosher* when prepared in a rigorously supervised manner, as attested to by an *orthodox* Rabbi.

(a) The Torah designates as *Kosher* only those animals that have cloven hoofs and chew their cud, and certain fowl. However, in order for this meat to be *Kosher* for consumption, they must be slaughtered in accordance with Jewish ritual, by an ordained *Shochet* (Ritual Slaughterer). Meat must be purchased only from a *kosher* butcher who is under supervision of rabbinical authority. The butcher must know and practice the art and laws of *treiberin*, which means the removal of all fat deposits and the fat and blood veins before selling the meat to any customer.

(b) Poultry is first eviscerated. The claws and tips of the wings cut off and the jugular veins severed or removed.

(c) The heart of both poultry and meat is cut open and the tips of the extremities clipped off, before soaking and salting (in a prescribed method specified by Jewish Law).

3. Only those fish that have both fins and scales are *kosher*.

4. The eating or cooking (in any form or manner) of milk and meat together is prohibited. All meat products and milk products are considered the same as their milk and meat origin. A Jewish home, as well as food manufacturers and processors must have two sets of dishes and utensils of different design and which are separately stored for dairy and meat diets. Meat and dairy dishes or utensils must not be washed together, nor even separately in the same basin.

5. Equipment used to produce non-kosher products cannot be used to process *kosher* products unless it is subjected to a *kosherizing* operation under the supervision of a qualified orthodox rabbi.

6. All *unadulterated and unprocessed* produce, such as fruits, vegetables, cereals, minerals—all things that grow from the soil, vines or trees—are inherently *Kosher*.

7. All manufactured products which may contain any ingredients derived from doubtful origins must be checked by a rabbinical authority as to whether the *Dietary Laws* were not violated during their preparation.

8. A neutral group of foods, which are neither of milk or meat derivation, like eggs, fruits, vegetables, cereals and fish are known as *pareve*. All of the above mentioned, except for fish, may be prepared with *milchig* (milk) or *fleishig* (meat) after which these cease to remain *pareve*. *Pareve* things also become either *milchig* or *fleishig*, according to the utensils used for their preparation.

9. *Kosher* fish is *pareve* and can be prepared for both *milchig* or *fleishig* use. While we are allowed to eat fish during a meat meal, it is forbidden to cook or serve both together. Fish must be served on separate dishes.

II. KOSHER SUPERVISION—NORMAL

1. In order to claim that a product is *kosher* (by appropriate designation on the package label, or otherwise), there must be certification, by an *orthodox* rabbi, that the *kosher* requirements have been met.

2. This is usually accomplished through a contract with a rabbi or *kashrus* certification organization who, through their regular inspection of the plant and food facilities and detailed knowledge of the formulas, various ingredients and their *originating* source, certify the products as *kosher*.

3. *Inert* as well as *active* ingredients must be of *kosher* origin. *Inert* ingredients are defined as emulsifying agents, binders, flavorings, dispersing agents, buffer substances, preservatives, colorings, dilutants, coatings, lubricants, fillers, disintegrators, etc.

4. During the canning season or production schedule the rabbi normally visits every cannery and every refinery several times. In these inspections he may review or ask questions about the processes, ingredients, and labels involved in any or all of the products produced at *that* location.

5. He also visits "corporate headquarters" where he consults with the "corporate staff" on any new products, formulas or *kosher* or *kashrus* problems which may arise.

6. A refinery or Food Production Facility which processes *kosher* and *non-kosher* products in equipment immediately adjacent to each other, is a special situation and requires *daily* supervision by an *orthodox* rabbi to assure that the "*kosher* item" produced there, and that all ingredients shipped from there to other refineries, are indeed *kosher*.

III. PASSOVER SUPERVISION

(a) The *Passover* season brings with it *all* the above Dietary laws, *plus* additional *Passover* rules in connection with the proscription of *Chometz* and *Chometz* products (described in (b) below).

(b) Each spring there is a special demand for *kosher* products which are *Kosher for Passover*. To qualify, an *otherwise kosher* product must, *in addition*, be *free* of the following grain products, by-products or derivatives and be packaged under the direct supervision of an *orthodox* rabbi:

(i) wheat (all classes) (*triticum aestivum* L) (*T. compactum* host) (*T. durum* desf)

(ii) Barley (*hordeum vulgare*)

(iii) Spelt (*Tricticum (emmer) diccicum*)

(iv) rye (*secale cereale*)

(v) oat (*avena sativa*)

(an example would be starch, ethyl alcohol, whiskey, all wheat flours, bulgar, semoline, farina, grain sorghums)

(vi) Dockage of items (i) through (v)

(vii) *legumes* (e.g. soybean oil, cake and meal, lecithin, peas, beans, corn syrup (e.g. glucose) etc.)

(viii) rice

IV KOSHER EQUIPMENT

1. Equipment which has *not* been used to process meat, meat fat or meat by-products (see 1-i above) is acceptable for processing *kosher* products. Hence, a cannery or vegetable oil refinery which *never* handles any meat by-products will normally produce *kosher* products.

2. Care must be taken, however, to maintain the *kosher* status of a plant by studiously avoiding the introduction of any animal derivative or secondary product containing animal derivative (See II 3 above) (e.g. emulsifiers) into the system. Once such contamination has taken place, the affected equipment must be *kosherized*, which can be an expensive, laborious process, involving washing, steaming, a 24 hour wait, and supervision of the process by an *orthodox* rabbi.

(a) In some simple processes, the *kosherizing* of the equipment to permit production of other products is easily done over a weekend.

(b) In more complex ones, such as a refinery deodorizer, where visual inspection of the *kosherized* equipment is almost physically impossible, and the time delays unacceptable, separate *kosher* and non-*kosher* equipment is absolutely necessary if both types of products are to be produced at the same location.

3. The above precautions with processing equipment must also be taken with tanks, tankcars, and tankwagons. Hence, any such vessels must be *kosherized* after they have contained animal fat, and *before* they can be used for *kosher* vegetable oil.

V. POLICY

Preferably, it should be the policy of food processors to identify their food products as *kosher* whenever appropriate and possible, and to have these products and the plants in which they are produced certified as *kosher* by a qualified *orthodox* rabbi or rabbinical organization.

VI. CERTIFICATION OF NEW PRODUCTS

1. When a new product is still in the concept stage, a marketing decision should be made by the manufacturer as to whether it should be a *kosher* product.
2. If yes, the product development personnel should prepare ingredient specifications calling for *kosher* ingredients and a process should be developed which is also *kosher*.
3. Before labels for the product are approved, (in which the *kashrus* symbol should be incorporated), the *orthodox* rabbi should be contacted and given full particulars as to the formula, the source and the nature of the ingredients, and the location and nature of the processing equipment. If these meet with his approval, permission is granted to use the *kashrus* symbol on the label of the packages.
4. The *orthodox* rabbi will usually want to be present at the first production run to personally verify that the ingredients and equipment are *kosher*.

בעזרת השם יתברך

ספר
שלום שלום לרחוק
ולקרוב ורפאתיו

בירור הלכה המבארת
יצירת התרופות הרפואיות,
וכשרותם לכל השנה (בכלל)
ולחג הפסח (בפרט).



יו"ל ע"י

הק' שלום יהודה גראס
אבק"ק האלמין
ברוקלין נוא יארק שנת תשנ"ח

קונטרס

שלום לרחוק ולקרוב ורפאתיו

בירור הלכה המבארת יצירת התרופות הרפואיות, וכשרותם לכל השנה (בכלל) ולחג הפסח (בפרט), אשר כשרותם בנויה ומיוסדת אך ורק מכתבי שאלות ותשובות בין הרבנים ובתי החרושת. ואף שלשון חכמים מרפא.

דרשתי וחקרתי היטב והנה נתאמתה הדבר שנעשתה שגגה בישראל בהסתמכות על קישור המכתבים. דרכיו ראיתי ואראהו, ועמדתי בעזה"ת על מהות תוצרתם האמיתי ותמציתה: כי אין לסמוך על מכתבים כאלו.

הו"ל בחמלת ה' עלי בזכות אבותי ורבותי הק' ז"ע

הק' שלום יודא גראס

דב דקהל, מגן שאול" ד, האלמין" ור"מ בישיבה וכולל, בית ישע"י
"מכון להוראה בשחיתות ובדיקות"

בעהמח"ס: אפיית המצות השלם (י' חלקים); גידולי יהודה (על הלכות ציצית); שו"ת זבחו זבחי צדק (על הלכות שו"ב); חינוך ישראל סבא (מדריך לחינוך הבנים והבנות); מדריך לצניעות; מזוזת שלום (על הל' מזוזה); מנחת שלום (הדרכה לכשרות); מנחת יהודה, (על חומר איסור, חלב עכו"ם ו"סימילאק"); נפש ישע"י (על מאכלות אסורות, ה"ח); קדושת ישראל (על הלכות יחוד); ושי"ס.

בלאמור-הרה"ג הצ' מוהר"ר ישע"י זאב גראס זצ"ל נכד השרף מסטרעליסק, ר' יעקב קאפיל חסיד, ט"ז, בית, תו"ט, רש"י, ולמעלה בקודש עד דוד המלך עה"ש.

- ברוקלין, יצ"ו • שנת תשל"ח -
- ההכנסה מוקדשת לטובת הישיבה והכולל -

שלום לרחוק ולקרוב ורפאתי

דיני סמי רפואה *

שאלה

יו"ד כסלו תשל"ז

שפעת חיים ושלוש וכ"ט לכבוד המאה"ה הרב
הגדול בתו"ש אוצר התורה המדריך עמו ישראל
באהבה וכו' כקש"ת מו"ה... שליט"א, מח"ס...

אחדשה"ט פונה אני למע"כ להורינו דרכי נועם דבר ה' זו הלכה.
נא אל יחר בעיני כהד"ג נ"י על אשר הטרחתי אותו במכתבי זה
ואנחנו מה להתיצב במקום גדולים ומהראוי לי להיות נחבא אל
הכלים ומה גם כי כבד לשון אני ולא ידעתי דבר בצחות מליצות
הלשון גם לאנשי ערכי ואף גם נגד שר התורה והחכמה כיו"ב. אולם
בזאת אזרתי חיל היות הדבר מצוה רבה וההכרח לא יגונה. ובטחוני
בצדקתו דמר מעכ"ת נ"י לבל יאמר נואש לדברי ח"ו ויעניני במחכ"ה
במוקדם האפשרי.

ברצוני לדעת אם והאיך יכולים בבירור לעשות רשימות ולדון
בעניני כשרותם של תרופות רפואיות לכל ימות השנה בכלל ולפסח
בפרט.

מפני הקשיים לסדר השגחה בבתי חרושת ולברר ולהבחין ע"י
בדיקות כימיות בין התרופות הכשרות לאותם שאינם כשרות
מוכרחים לשלוח מכתבי בקשה לגורמים רפואים שונים - משרדי
השלטונות, בתי מרקחת ורפאים שונים, הסתדרות הרוקחים
והרופאים, טובי הרופאים, כימאים ורוקחים - לבקש עזרתם בנדון
זה אני מדגיש שאין ביקור בשום ביח"ר... הכל בנוי ממכתב
תשובתם.

ועל של עתה באתי בשאלותי לדעת האם יכולים לסמוך ולתמוך
יסודות על תשובתם אף לדבר היתר, או רק באופן שלילי (היינו שהם
כותבים שהפרמבצבטיים כוללים חומרים או יצורים בלתי כשרים);
ושנית אם מותר או נכון לפרסם תוכן ותמציות מכתבם באופן שרבים
יסמכו על זה?

ובפסענו מן הקודש תבענה שפתי תפלה לשוכן מעונה, שיאריך
ה' ימי מע"כ שליט"א וברוב אונים יאמיץ כח יזכה להתענג על ה'
בעבודתו הטהורה מתוך בריאות, תענוג והרחבת הדעת דקדושה עדי
נגאל גאולת עולם בקבלת פני משיח צדקינו עם מנהיגי הדור בראשנו
בב"א נצח סלה ועד.

כעתירת וברכת זד"ח בברכה המשולשת

תשובה

מילתא אלכישוייהו יקירא!
אם יהיו כל הימים דיו ואגמים קולמוסים ושמים יריעות וכל בני

אדם לבלרין אין מספיקים לכתוב חללה של רשות" (שבת י"א).
 (כלומר: קשה לכתוב כל הדברים שהממשלה צריכה לדאוג ולטפל
 בהם) שנאמר שמים לרום וארץ לעמק ולב מלכים אין חקר. ופירש
 המאירי: מוטלת על הרשות חובות רבות כל כך שקשה לאדם רגיל
 להעריכן.

בכתובת פרק זה על עניני התרופות התקשרתי עם מנהלי כל
 בתי חרושת פרמבצבטיים בארצות הברית לדעת, על בוריין, כל
 הדברים הנוגעים לעניני העשייה (התוצרת) והמסתעפים לדיני
 הכשרותם. דבר אחד וגדול למדתי מכולם שאי אפשר לעמוד בבירור
 על תוכן התרופה לזמן מרובה – ולפעמים אף לזמן קצר – כי מעשה
 התוצרת (היצירה – Manufacturing Process) ותוכן התרופה
 (Ingredient Origin) משתנה בכל עת ורגע, וגם בתרופה אחת יש
 נפקא מינה באיזה חלק מארצנו נוצרה – בצד מזרח, מערב, צפון
 ודרום.

עיוני בדבר היתה בנויה על השאלה:

regarding the presence of various animal and grain derivatives in our
 products for purposes of determining whether these conform with
 Jewish Dietary Laws.

וצרפתי להשאלה שני מכתבים כללים המסבירים, בקיצור, כל
 ההלכות המסתעפים לדיני הכשרות (ראה Appendix I).
 דע נא: כל רב ומורה הוראה המובהק לכך מוכרח לדון בשני
 סייגי תרופות:

- 1) אותם שנצטוו על ידי רופא (Prescription).
- 2) אותם שכל אחד יכול לקנות לבדו בחנות הרוקח „עובר
 לסוחר“ (Over-the-Counter-Drugs).

אין כל ספק שאותם התרופות הנמכרים „עובר לסוחר“ אין היתר
 לקחת אותם באם שהם מכילים „מאכלות אסורות“, כיוון שעליהם חל
 הדין: „איכא דרכא אחרינא“.
 לפי חשבון המשלה נמצאים תרופות כאלה בארצות הברית,
 כהיום, בסכום 350,000.

בתרופה הנתונה על פי „צו רופא“ יש מקום להסתפק אם החולה
 יש בו סכנה או לא, אי איכא דרכא אחרינא או לא, אי יכולים
 להחליף התרופה שנצטוו עליה (ושמכילה דבר האסור) בשניה שאין
 בה חומר (האסור) זה.

אך זאת למודעי שאין שאלה בדברים שהם

medicinals which are critical to the health of an individual or to in-
 dications which are serious in nature.

שלום לרחוק ולקרוב ורפאתיו

(א) שינוי החומר מעת לעת ומפקידה לפקידה
 1. ראשית דבר, תוצרת כל תרופה משתנה בכל עת.
 מובא פה, בלשונם, דברי בתי החרושת הכי גדולים בעולם.

ABBOTT PHARMACEUTICAL PRODUCTS DIVISION
 ABBOTT LABORATORIES

...regarding specific ingredients in specific products. I am sure you are aware of the great amount of time required to check the formula of all the Abbott products to see if they contain... (prohibited substances). Not only would the final formula have to be checked, but the formula for many of the ingredients (also) to see if they contained these prohibited substances.

We prefer that such lists not be made due to the frequency with which our products formulas change. At any time a product may be reformulated and have the prohibited substance removed. More importantly, a product not on the list could have the prohibited ingredient added.

General or specific statements cannot be made for so many varied products.

בתרגום חפשי: אף אחרי שכתבנו שתרופה, ג'קיה" ממאכלות אסורות, יכול המצב להשתנות, ומאז מכילה התרופה חומר בלתי כשר.

PARKE, DAVIS & COMPANY:

וכן כתב גם:

Parke-Davis has several hundred products which might be used in treatment. I hope you will understand that it is impossible for us to give you a complete breakdown of all components and also that they may be subject to revision from time to time because of various reasons.

בתרגום חפשי: חומר התרופות משתנות מעת לעת מכמה טעמים...
 אי אפשר להגיד ולדעת בפרטיות מה התרופה כוללת.

SYNTEX RESEARCH
 DIVISION OF SYNTEX (U.S.A.) INC.
 INSTITUTE OF PHARMACEUTICAL SCIENCES:

Many components are used in compounding pharmaceutical formulations. These materials might be animal, vegetable, and/or mineral in origin. Many of these ingredients are produced by reactions of other chemical materials, and so attempting to learn whether any animal materials were used in the manufacture of a product becomes a complex maze. It would require a skilled detective to unravel some of the intricacies of the reactants which are utilized, and I think that the answer might often depend more on zeal, orthodoxy, and Talmudic interpretation than on mere catalogue listings.

In regard to grain products, in tableting we also employ such materials as wheat starch and corn starch. I question whether you could obtain more than a few tablets on the market which did not contain some corn starch. Wheat starch is much less commonly used. Furthermore, any products which contain alcohol such as elixirs and some cough syrups would contain grain alcohol.

שלום לרחוק ולקרוב ורפאתי

1

(ב) קישוי הבחנת החומר

על דבר קישוי הבחנת כשרותה של איזה תרופה הבאה מיריעת
חומרי ההרכבה, הסבירו:

CIBA-GREIGG CORPORATION
PHARMACEUTICALS DIVISION

An effort to determine which of our products are kosher and which are not would be a monumental task. In addition, I doubt whether any company has products which would be considered as kosher unless it had made a concerted effort to manufacture them.

תוכן המכתב בקיצור: אני מסופק אם יש איזה ב"ח שתרופותיה
כשרות בלי, "התאמצות מיוחדת" על ידה לייצר אותם באופן "כשר".
וליתר שאת ותוכף עזו אמרו אודות צור מחצבתם של החומרים
השונים:

SYNTEX RESEARCH
DIVISION OF SYNTEX (U.S.A.) INC.

I consider the impossibility of tracing the origin and geneology of materials such as surface active agents, fats and alcohols. To further compound the problem, the same chemicals purchased from different manufacturers can be made by many different processes and may have utilized many different intermediates. You have a scientific recognition of the enormity of the problem of ever being able to say that a particular chemical of commerce did or did not comply with the standards of kashruth...

...there is no way in which we can determine the sources of origin of these materials or how they were prepared. Neither could we guarantee that the materials will be purchased each time from the same manufacturer.

תוכן המכתב בקיצור: אי אפשר בשום פנים להבחין שורשה של איזה
חומר ויצירתה... גם אי אפשר להיות ערב שבכל פעם נקנים
הדברים מאותו ביה"ח.

(ג) טהרת החומרים על פי צו הממשלתי

בתי החרושת מסבירים שהם אחראים לשמור על טהרת החומרים
והתרופות רק לפי אותה מדה שנצטוו לפי חק הממשלתי,
הדורשת

They all have to meet the highest compendial standards of purity.

והיינו בלשונם, שנוצרים על פי

"United States Pharmacopoeia or National Formulary".

אכן, שם מדובר אך ורק על מעשה ה"כעמי" ונקייתה מדברים חצונים
המזיקים לחומר ה"כעמי" (כגון "באקטיריע") - אבל לא על שורשה
מאין באתה

CIBA-GREIGY CORPORATION
PHARMACEUTICALS DIVISION

ונן כתבו:

I can tell you that as a general rule the majority of tablets and capsules contain either magnesium or calcium stearate. The source of this stearate can be either animal or vegetable fat, but no major pharmaceutical company, to the best of my knowledge, makes a conscious attempt to control the material which they receive to one type or the other. The criteria for acceptance or rejection is based on the stearates meeting company specifications usually related to the United States Pharmacopoeia or National Formulary.

תוכן המכתב בקיצור: זה אני יכול לומר שבדרך כלל רוב הכדורים
(טאבלט) והנרתיקים (קאפסול) יש בהם, מגניזיום או קלסיום

שלום לרחוק ולקרוב ורפאתיו

סטירעט" שנעשים מחלב (בצירי) בהמה (חיה) או עשב... אבל לפי דעתי אין שום ביח"ד המייצרת תרופות יודעת מאיזה דבר שורשה של החומר שלהם שבו הם משתמשים... יודעים רק שהחומר נקי ונעשה על פי חוקי הממשלה.
וב"ברים האלה ג"כ אמרו (שאין הממשלה דורשת מאין תהי' שורשה של החומר בה משתמשים).

CHESEBROUGH-POND'S INC.:

All ingredients used in our products meet fully the standards and specifications that have been established in the official compendia or that are recognized as assuring their quality, strength and purity. I am sure that you understand that these standards are not specific in regard to the sources of certain ingredients. For example, ethyl alcohol can be derived from starches (wheat, corn or potato), sugars (cane or beet) or prepared synthetically. Similarly, glycerin can be derived from vegetable oils, animal fats or prepared synthetically. Furthermore, certain processes used to prepare ingredients from their source materials are essentially chemical syntheses that result in a new chemical entity. Our purchasing specifications do not generally require that such ingredients be from a particular source or derived by a particular process. בתרגום חפשי: אין אנו דורשים או שואלים מבתי החרושת שמהם אנו קונים החומרים צור מחצבתם ויחוסם של החומרים או באיזה אופן נוצרו.

ואף אחר שבית החרושת ענתה בווראות שתרופה מיוחדת אין בה חומר הבאה ממאכלות אסורות, ובשעת ענייתם ידעו בבירור על מה ולמה אנו כהבנו להם (ואין כאן משום „מסיח לפי תומו“).

STUART PHARMACEUTICALS, DIVISION OF ICI AMERICA, INC.

We assume that your main interest in our products is to determine which of these can be considered as kosher for daily use, and which might also be suitable for Passover purposes.

אנו לומדים מתשובתם שבהערתם מתעוררת לנו שאלה נוספת הצומחת מגוף „מעשה היצירה“ של התרופה במכונותיהם:

"Acceptability" from a Kosher standpoint is based on the nature of the ingredients. It must be recognized that the equipment used by the manufacturer of the raw materials employed in these products or by Stuart Pharmaceuticals in manufacturing these products, even though thoroughly cleaned, may not qualify as Kosher because of previous contact with non-Kosher products.

"Acceptability" for Passover is based on the nature of the ingredients. The possibilities exist that the equipment used by the manufacturer of the raw materials or by Stuart Pharmaceuticals in manufacturing these products, even though thoroughly cleaned, may have been in previous contact with other products containing grain-derived materials.

זאת אומרת:

- (א) הם קונים חומרים („אינגרדיענטס“) מבתי חרושת אחרים שאינם יודעים טבעם ומעשה תוצאותיהם: ויכול להיות שיש בהם דברים אסורים.
- (ב) אף שהם נקיים מחומרים ששורשם מאכלות אסורות, אכן נוצרו במכונות שבהם נוצרו ונשתמשו בהם מקודם מאכלות אסורות.
- (ג) בעייה זו חלה בין על בית חרושת „הגומרת“ התרופה ובין בזה שמסדרת החומרים השונים ומוכרת אותם לאחרים לייצר מהם כרצונם.

שלום לרחוק ולקרוב ורפאתי

ח

סכום

דברי סכום לדברינו הנ"ל נאמרו כאופן ברור כדברים האלה: אי אפשר לבית חרושת המייצרת התרופה לדעת תוכנה ואיכותה של כל החומרים השונים:
ABBOTT PHARMACEUTICAL PRODUCTS DIVISION:

...concerning ingredients used in various medicinal products. We have several hundred formulas and we are not in a position to go through them in detail to determine all of the ingredients used in them.

It is true that we use animal products such as gelatin in many of our products. In addition, stearates, which are usually derived from the animal fat, are frequently used. Lactose from milk, corn starch and alcohol from grain and many other agents are used. Frequently we are purchasing these items from outside vendors and do not know the originating source of many of these items. Sometimes the product can be derived from natural sources or synthesized. We make no distinction in purchasing between these two sources and do not have available to us the information you request.

כתרגום חפשי: אנו קונים חומרים מבת"ח אחרים ואין אנו יודעים ממה נעשו. אין זה נפקה מינה לנו ואף אם תשאלו אין אנו יכולים לענות.

(ד) נקוי הכלים

גם נקוי הכלים ושמירתם מליכלוך נעשה רק כדרגה הממלא צו חק הממשלתי, אשר אינה כנויה על נקיון ובשרות הכלים" שממלא צו חק התורה הקדושה.

CHESEBROUGH-POND'S

CHESEBROUGH-POND'S INC.

In regard to manufacturing and processing equipment, we use separate equipment for each product, except in a few cases where products are essentially similar in basic composition. All equipment is routinely cleaned and sanitized in accordance with currently accepted good manufacturing practices for drug products.

(ה) חומר הנרתיקים והכדורים

בעיית נרתיקי התרופות הנקראים "קאפסול" כלע"ז קשה לפתור. אלה הם דברי:

STUART PHARMACEUTICALS
DIVISION OF ICI AMERICA INC.

...regarding a "capsule" and the possible freedom of our capsulated products from any animal derivatives. Since almost all of the capsulated products manufactured in this country contain gelatin as the capsulating material, it is apparent that none of these products (either ours or those of other manufacturers) are free of animal (mammalian) derivatives. Indeed, we are not aware of a source of capsules where the gelatin is derived from kosher sources, e.g., kosher-killed animals or fish.

זאת אומרת, כולם נוצרים ממאכלות אסורות!
ועוד כתבו לכלול ג"כ כדורים ("טאבלעט") כדבר:
ועוד כתבו, לכלול ג"כ כדורים ("טאבלעט") בדבר:
כתרגום חפשי: כמעט שכל הנרתיקים (קאפסול) עשויים מג'לטין...
ואף אחד משלנו או של איזה תרופה או בית חרושת אחרת אינה נקויה ממאכלות אסורות! אין אנו יודעים אף מקום אחד שנעשה ממאכלות כשרות.

ט

שלום לרחוק ולקרוב ורפאתיו

SQUIBB

Small amounts of stearic acid or magnesium stearate are used in most capsule and tablet formulations. In nearly all cases, it would be derived from animal sources.

בחרגום חפשי: ברוב מקרים נעשים, מגניזיום סטירעט" ממאכלות אסורות

MILES LABORATORIES, INC.

וכן, לדוגמא, כתבו גם אחרים:

Small amounts of animal-derived substances (magnesium stearate and gelatin) are employed in many tableted products as lubricants and binders.

A.H. ROBINS COMPANY

וברברי

...alcohol could either be synthetic or might be derived from grain.

...glucose is derived from starch which might be corn.

...glycerin could at any one time be from animal, vegetable or synthetic sources and it would be impossible to state that the animal source was not porcine.

בחרגום חפשי: גליצרין" יכולה להיות בכל עת ורגע מדבר כשר או מטרפות ואי אפשר לדעת בשום אופן אם אינה טרפה

...magnesium stearate is synthesized from stearic acid which is derived from animal fats.

BOEHAINGER INGELHEIM

וברברי

Gelatin - derived from the skin, white connective tissue and bones of animals.

Stearic Acid - derived from the fat of cattle and sheep.

STUART PHARMACEUTICAL PRODUCTS

וברברי

magnesium stearate (source of stearic acid while known to be of vegetable origin is unknown as regards grain or acceptable seeds, (e.g. cottonseed or peanuts).

psyllium is derived from psyllium seed which is not considered to be a grain.

flavors dissolved in ethyl alcohol; source unknown.

vegetable-oil derived stearates of unknown origin.

שלום לרחוק ולקרוב ורפאתיו

7

(ו) בכמות חומר (אינגידיענט) האסור בתרופה

פתור השאלה לדעת שיעור כמות שיעור האסור בתרופה כולה בכדי להבחין מזה האם נבטל ב„שישים“ ג"כ איננה כל כך פשוטה:

STUART PHARMACEUTICALS
DIVISION IF ICI AMERICA INC.

The question as to whether the percentage of gelatin is less than 1.5% of the gross weight of the tablet or of the volume of the tablet appears to be moot, since it has been my assumption that it is not the concentration of gelatin which is important, but rather the source. The gelatin in our products is from animal (mammalian) sources and is non-Kosher.

(ז) סמכות על מכתבי מנהלי בתי החרושת

יסוד ה„מסיח לפי תומו“ של תשובותיהם של מנהלי בתי החרושת, שעליהם אנו בונים בנינים גבוהים ורמים, מקולקלת. לדוגמא, אנו כתבנו לבית חרושת בנוסח בהיר, קל וצח במכתב מודפס (תצלום ממכתבים מובאים בסוף הפרק). ואעפ"כ תשובתם היתה:

SANDOZ PHARMACEUTICALS

...we are returning the completed schedule for "Ingredient Identification"

...dilutant: lactose

...lubricant: stearic acid, calcium stearate

Notes:

- a) lactose is a sugar derived from milk; it is questionable as to whether it is actually a milk by-product.
- b) stearic acid and calcium stearate are tallow derivatives, usually obtained from cattle and sheep. They are refined to the extent that "meat" is not present.

בתרגום חפשי: „ספיריק עסיר“ נעשה מחלב (בצירי) אך אין שם בשר בעין.
נראה מזה שאף שכתבנו להם בקשתנו בלשון ברור, תשובתם נתונה לפי הבנתם בדברים. לדעתם, אם לא נתנו בדבר בשר ממשי (גוש) אין בתוצר דבר בשרי.

(ח) דין בשר בחלב

שאלה נוספת נולדת לנו מדיני בשר בחלב. והיינו לבד מאיסור חלב סתם של עכו"ם שאסרוהו רוב הפוסקים כמבואר בספרי „נפש ישעיה“ באורך ושני בספרי „מנחת יהודה“, אלא אף אם יש רב ומורה הוראה המתיר חלב עכו"ם (או חלב „סתם“), אבל שאלתנו המקורית היא אם מותר לאכול תרופה חלבית זו יחד עם מאכל בשר ממשי (בעין), או בזה אחר זה וכו'. מעניין שביית חרושת אחת בעצמה הבינה דבר זה ועמדה עליה וכתבה לנו:

שלום לרחוק ולקרוב ורפאתיו

CIBA-GREIGY CORPORATION
PHARMACEUTICALS DIVISION

My rabbi has informed me that today the majority of animals are slaughtered under kosher conditions. However, we cannot be a hundred percent certain about our material. In addition, most tablets and capsules also contain lactose as an excipient. Lactose, being milk sugar, would represent a dairy item and if combined with magnesium or calcium stearate from animal source would be comparable to mixing dairy and meat products together.

והוסיפו שרבר זה קשה למלאות:

Thus the only way you could be certain of obtaining tablets and capsules which would meet with the laws of "Kashrus" would be for a company to make a concerted effort to use only stearates manufactured from vegetable source, or to use only stearates obtained from animals which have been killed under kosher conditions, and at the same time exclude the use of milk sugar as one of the dosage form excipients, or as a special research project, to develop a series of new (possibly inorganic) excipients which would fall into a neutral area and be excluded from the laws of "Kashrus."

חד מהכותבים. שצור מחצבתו מבית ישראל, כתב:

We obtain our stearates from a number of suppliers, some of whom tell us they are supplying material from animal fat, others from vegetable oils. Therefore some lots of our products may be made with purely vegetable material, other lots with animal fats. Furthermore, even if we controlled certain products putting into them only the vegetable fat, they would be manufactured on the same equipment which is used to manufacture that containing animal fats. In my opinion this would be comparable to someone who keeps a kosher home and then intermixes the dairy and meat cooking utensils...

בתרגום חפשי: אף אם נדע שמשמשים בחומר כשר, אכן תוצרותיהם היא במכונות שמקורם לכן נשתמשו בדברים האסורים... ויכול להיות תערובות... כמו, "בשר בחלב". וסיים במכתבו.

"Although I am presently a member of a reform congregation, I came from an orthodox family who attended an orthodox synagogue. It was always my understanding that the laws of the "Kashrus" were waved in cases which involved the health of the individual. I have recently discussed this matter with my, as well as other rabbis and have been informed that the Torah does state this in regard to the health of the individual. I was wondering if there is a newer interpretation and therefore the concept of health coming before "Kashrus" is no longer considered to be valid."

דברי סיכום לכל המכתבים יכולים למצוא בדברים המובאים שמסבירים שכל בתי הרושת לתרופות, כולם פה אחד להם ומעשה אחת לכולם ודעותיהם מכוונים ואינם שונות זו מזו:

שלום לרחוק ולקרוב ורפאתיו

יב

BRISTOL LABORATORIES
BRISTOL-MYERS COMPANY

...information on the source of materials used in various types of medications:

In general, I think you will find that most pharmaceutical manufacturers tend to use the same general types of ingredients in similar product groupings.

One notable exception is the fact that sucrose, which is used in relatively high concentrations in syrups and powders for reconstitution with water, is primarily derived from sugar cane if the material is used in the East and South, and from beets if the sucrose is used in the Midwest or West. In our case, all of our sucrose is obtained from cane. In general, the flavors and colors used in syrups and tablets are of artificial origin.

Lactose is commonly used in tablets and capsules as a filler. This material, of course, is derived from milk. Most tablets also contain corn starch. Capsules, of course, are made of gelatin, which is of animal origin.

The other materials you mentioned in your letter, such as buffers and preservatives, are generally produced by chemical synthesis.

I hope that the above information, although necessarily general in nature, will be of some help to you.

מלת „דוענעראל“ מתורגמת: „בדרך כלל“. זאת אומרת שהדבר נעשה באופן מסוים בדרך כלל אבל אין מדויק על ידי המייצר שזה נעשה באופן הרשום בכל פעם היינו מאה אחוז (100%). וא"כ האיק נסמוך על דבר כזה.

(ט) פירות הנושרים להלכה

אחריות גדול הוא לעשות רשימה מתרופות הכשרות (בכלל) ולחג הפסח (בפרט) מאחר שמשנתים אופני העשייה, החומרים ותוצרותיהם מעת לעת ומפקידה לפקידה; ומה עוד שקשה לעשות רשימה מיוחדת לחג הפסח מאחר שהיא כתובה כמה חדשים לפני החג – שמעת כתיבתה עד החג היא אפשרות להוולד השתנות בהתרופה, ומה עוד שהרבה מהתרופות מונחים מוזמן כבר בבית המרקחת (דראג סטאר) ואי אפשר לדעת מאיזה „יורה“ באה החומר שממנה נוצרה התרופה.

אין לנו להשען כי אם על הרב המורה הוראה – המובהק לכך – שיפסק הלכה למעשה למי ששואל כענין; והמורה ישקל במאזני שכלו לפי רצינות מצבו של החולה בלי הסתמכות כלל על ידיעת תוצאת התרופות, כי אין לעמוד על אמיתתן כאשר בידרתי כאן וכל יחיד כמובן יש לו דין בפ"ע, וא"כ דעת לנבון נקל שא"א לדרוש לרבים וכ"ש להדפיס שום רשימה כללית או פרטית להקל להמון בית ישראל אכילת תרופות וסמים לרפואה או להחזיק חולשת הגוף.

שלום לרחוק ולקרוב ורפאתיו

יג

אין בית החרושת מרגישים כהשתנות מקור וצור מחצבתם של החומרים בו הם משתמשים בעשיית התרופות. אי אפשר לומר „דיין שעתן“ כי אנו צריכין לחוש שמה התחילה „השינוי בזמן מוקדם (או מאוחר) יותר. גם קשה לומר „מפקידה לפקידה“ (מכדיקה לכדיקה) ולהורות לשואלים שביון שאין ידוע מתי התחילה השינוי בתרופה הריהי נחשבת טרפה למפרע ככל הזמן שעבר משעת הבדיקה (ע"י מכתב) האחרונה שדקנו אותה ומצאוה בשרה (ע"י המכתב). אפילו הייתה בדיקה זו לפני זמן רב – מאחר שהשינויים בתוצר החומר חלים ככל יום ויום. גם קשה לומר „לא בדברי זה ולא בדברי זה“ ולבלול הדבר: „מעת לעת ממעט על ידי פקידה לפקידה“ (בלומר אם בדקו התרופות (ע"י מכתבים) לפני זמן רב אין אנו צריכין לחשוש אלא ליממה האחרונה זאת אומרת מעת הבתיבה (התשובה) והלאה); או „מפקידה לפקידה ממעט על ידי מעת לעת“ (שאם בדקו (ע"י המכתב) בתוך יממה הרי קודם לשעת הבדיקה ודאי שהיא כשרה. ולמה? מפני שאמרו בפירוש שאי אפשר להם לדעת בכירור מאין בא (נוצר) ולאן הולך (במכונה) החומר.

אמרו חז"ל (שבת יו"ד) שכל דיין שדן דין אמת לאמיתו אפילו שעה אחת מעלה עליו הכתוב כאילו נעשה שותף להקב"ה במעשה בראשית. ופירש ב„נתיבות עולם“: ההדגשה זו באה להבליט כי לא די שהמשפט יהא אמת לפי טענות בעלי הדין או לפי מסקנות ההלכה. אלא שיהא הדין בטוח שדרך זו היא האמת!

ועל בן אמרו חז"ל (שבת י"ב): הלכה ואין מורין בן. פירוש: כי יש דברים המותרים, ותלמיד חכם היודע את היתרם – נוהג בן. אבל אין מפרסמים את הדבר ברבים („מורים“) כדרשה (או רשימה), שיכול הדבר להביא להכשלת הרבים.

אני תפלה לה' הרופא כל בשר שישלח רפואה שלמה כמהרה לכל חולי ישראל ויקוים הבטחתו ית"ש „בל המחלה אשר שמתו במצרים לא אשים עליך כי אני ה' רופאך“.

ויבוטל מעלינו כל גזירות קשות ורעות להתברך בששון ושמחה ישועה ונחמה פרנסה טובה וכלכלה לחיים טובים ולשלום ולגאולה קרובה. אמן.

כברכת חג הפטח בשר ושמח

מובא כאן תצלום מחלק של השאלון שבו השתמשתי בבירור תעשית התרופות. הקורא יראה שבדרך נפלא יגענו ומצאנו לצמצם עיקרי דינים הנוגעים לכשרות בשני הדפים וכאשר עבר מבחן מפורט מכמה גדולי ההוראה וגאוני התורה בדורנו, הסכימו לנו שהצליח ה' דרכינו. השאלון גופא הוא גדול בכמות ואיכות ונסדר (ע"י אחד מאנ"ש גדול ההוראה יר"ש ובעל מדע) באופן שאין להעונה מקום לטעות בתשובותיו בכל פרט ופרט מיצירת תרופה החל מיצירת החומר עד הנחתה בקופסא למכירה כולל כל תעשייה (אף שהיא דקה מן הדקה), וכל חומר שיש לה תפקיד מיוחד (יהי מה שיהי) למלאות מגמה מיוחדת זאת אומרת למשל:

Disintegrator, Emulsifier, Binder, Flanovring,

dispersing agent, buffer substance,

Preservative, coloring dilutant, coating,

Filler, lubricant... (ועוד הרבה כהנה)

אך, הואיל ורבים הם, אי אפשר לפורטם על כן שמנו פה לעיניכם רק חלק ממנו.

APPENDIX I

INGREDIENT IDENTIFICATION FOR KASHRUS PURPOSES

International Kashrus Association: 1/5737

INSTRUCTIONS

Insert in each box the name of the ingredient and the applicable code number and letter, as indicated below, to identify the kashrus of the product.

1. (a) Contains meat or the by-products and derivatives of: animal fowl, mammal, reptile, amphibians, insects, worms, fish not bearing fins or scales, or wine.
- (b) Free of the above products, by-products or derivatives.
2. (a) Contains milk, milk by-products or derivatives.
- (b) Free of the above.
- (a) Was processed in equipment which previously processed the above enumerated meat, meat by-products, or derivatives of: animal, fowl, mammal, reptile, amphibians, insects, worms, fish not bearing fins or scales, or wine.
- (b) Was processed in equipment which previously processed milk, milk by-products or derivatives.
- (c) Was not processed on such equipment.
4. (a) Contains the following grain products, by-products or derivatives: wheat (all classes) (*triticum aestivum* L) (T. Compactum host) T. durum desf.), barley (*hordeum vulgare*); spelt (*triticum (emmer) dicocum*); rye (*secale cereale*); oat (*avena sativa*); (an example would be starch, ethyl alcohol, whiskey, all wheat flours, bulgar, semoline, farina, grain sorghums); dockage of items (i) through (v); legumes (e.g. soybean oil, cake and meal, lechitin, peas, beans, corn syrup (e.g. glucose) etc.); rice.
- (b) Does not contain any of the above.
5. Free of any ingredient which fails to comply with items (1) through (4).

BASIC LAWS OF KASHRUS

KOSHER denotes that which is usable, suited for use or permitted as food pursuant to the Jewish Dietary Laws. The antonym is *treife*. Food, as well as medicinal products, require kashrus supervision.

Briefly stated, the policy and obligations of food processors *vis a vis* kosher food production, are as follows:

I. DEFINITION AND PROCEDURE

In general, products are eligible for *Kosher* certification if they meet the following criteria:

1. *Active and inert* ingredients are:
 - (a) free of:
 - (i) meat, meat fat or meat by-products of animal, fowl, mammal, reptile, amphibians, insects or worms, and fish not bearing scales or their derivatives.
 - (ii) milk, milk by-products or derivatives
 - (iii) wine, wine by-products or derivatives
 - (b) processed in equipment which has *not* processed the above enumerated meat, meat fat, meat by-products or derivatives, milk, milk by-products or derivatives, fish not bearing scales, or wine, wine by-products or derivatives.
 - (c) free of any *ingredient* which fails to comply with (a) or (b) above.

Examples of non-kosher foods are: *ova* eggs, gelatin, shellfish, cognac, brandy, bread baked in pans greased in fat.
2. Meat or meat by-products, as well as milk and milk by-products are *kosher* when prepared in a rigorously supervised manner, as attested to by an *orthodox* Rabbi.
 - (a) The Torah designates as *Kosher* only those animals that have cloven hoofs and chew their cud, and certain fowl. However, in order for this meat to be *Kosher* for consumption, they must be slaughtered in accordance with Jewish ritual, by an ordained *Shochet* (Ritual Slaughterer). Meat must be purchased only from a *Kosher* butcher who is under supervision of rabbinical authority. The butcher must know and practice the art and laws of *treiferin*, which means the removal of all fat deposits and the fat and blood veins before selling the meat to any customer.
 - (b) Poultry is first eviscerated. The claws and tips of the wings cut off and the jugular vein severed or removed.
 - (c) The heart of both poultry and meat is cut open and the tips of the extremities clipped off, before soaking and salting (in a prescribed method specified by Jewish Law).
3. Only those fish that have both fins and scales are *kosher*.
4. The eating or cooking (in any form or manner) of milk and meat together is prohibited. All meat products and all milk products are considered the same as their milk and meat origin. A Jewish home, as well as food manufacturers and processors, must have two sets of dishes and utensils, of different design and which are separately stored, for dairy and meat diets. Meat and dairy dishes or utensils must not be washed together, nor even separately in the *same* basin.
5. Equipment used to produce non-kosher products *cannot* be used to process *kosher* products unless it is subjected to a *kosherizing* operation under the supervision of a qualified orthodox rabbi.
6. All *unaltered* and *unprocessed* produce, such as fruits, vegetables, cereals, minerals—all things that grow from the soil, vines or trees—are inherently *Kosher*.
7. All manufactured products which may contain any ingredients derived from doubtful origins must be checked by a rabbinical authority as to whether the *Dietary Laws* were not violated during their preparation.
8. A neutral group of foods, which is neither of milk or meat derivation, like eggs, fruits, vegetables, cereals and fish are known as *pareve*. All of the above mentioned, except for fish, may be prepared with *milchig* (milk) or *fleishig* (meat), after which they cease to remain *pareve*. *Pareve* things also become either *milchig* or *fleishig*, according to the utensils used for their preparation.
9. *Kosher* fish is *pareve* and can be prepared for both *milchig* or *fleishig* use. While we are allowed to eat fish during a meat meal, it is forbidden to cook or serve both together. Fish must be served on separate dishes.

II. KOSHER SUPERVISION—NORMAL

1. In order to claim that a product is *kosher* (by appropriate designation on the package label, or otherwise), there must be certification, by an *orthodox* rabbi, that the *kosher* requirements have been met.
2. This is usually accomplished through a contract with a rabbi or *kashrus* certification organization who, through their regular inspection of the plant and food production facilities and detailed knowledge of the formulas, various ingredients and their *originating* source, certify the products as *kosher*.
3. *Inert* as well as *active* ingredients must be of *kosher* origin. *Inert* ingredients are defined as emulsifying agents, binders, flavorings, dispersing agents, buffer substances, preservatives, colorings, dilutants, coatings, lubricants, fillers, disintegrators, etc.

4. During the canning season or production schedule the rabbi normally visits every cannery and every refinery several times. In these inspections he may review or ask questions about the processes, ingredients, and labels involved in any or all of the products produced at that location.
5. He also visits "corporate headquarters" where he consults with the "corporate staff" on any new products, formulas or *kashrus* problems which may arise.
6. A refinery or Food Production Facility which processes *kosher* and *non-kosher* products in equipment immediately adjacent to each other, is a special situation and requires *daily* supervision by an *orthodox* rabbi to assure that the "*kosher* item" produced there, and that all ingredients shipped from there to other refineries, are indeed *kosher*.

III. PASSOVER SUPERVISION

- (a) The *Passover* season brings with it *all* the above Dietary Laws, *plus* additional *Passover* rules in connection with the proscription of *Chometz* and *Chometz* products (described in (b) below).
- (b) Each spring there is a special demand for *kosher* products which are *Kosher for Passover*. To qualify, an *otherwise kosher* product must, *in addition*, be *free* of the following grain products, by-products or derivatives and be packaged under the direct supervision of an *orthodox* rabbi:
 - (i) wheat (all classes) (*triticum aestivum* L) (*T. compactum* host) (*T. durum* desf)
 - (ii) Barley (*hordeum vulgare*)
 - (iii) Spelt (*triticum [emmer] dicocum*)
 - (iv) rye (*secale cereale*)
 - (v) oat (*avena sativa*)

(an example would be starch, ethyl alcohol, whiskey, all wheat flours, bulgar, semoline, farina, grain sorghums)
 - (vi) Dockage of items (i) through (v)
 - (vii) *legumes* (e.g. soybean oil, cake and meal, lechitin, peas, beans, corn syrup (e.g. glucose) etc.)
 - (viii) rice

IV. KOSHER EQUIPMENT

1. Equipment which has *not* been used to process meat, meat fat or meat by-products (see I-1 above) is acceptable for processing *kosher* products. Hence, a cannery or vegetable oil refinery which *never* handles any meat by-product will normally produce *kosher* products.
2. Care must be taken, however, to maintain the *kosher* status of a plant by studiously avoiding the introduction of any animal derivative or secondary product containing animal derivative (see II 3 above) (e.g. emulsifiers) into the system. Once such contamination has taken place, the affected equipment must be *kosherized*, which can be an expensive, laborious process, involving washing, steaming, a 24 hour wait, and supervision of the process by an *orthodox* rabbi.
 - (a) In some simple processes, the *kosherizing* of the equipment to permit production of other products is easily done over a weekend.
 - (b) In more complex ones, such as a refinery deodorizer, where visual inspection of the *kosherized* equipment is almost physically impossible, and the time delays unacceptable, separate *kosher* and *non-kosher* equipment is absolutely *necessary* if both types of products are to be produced at the same location.
3. The above precautions with processing equipment must also be taken with tanks, tankcars, and tank-wagons. Hence, any such vessels must be *kosherized* after they have contained animal fat, and *before* they can be used for *kosher* vegetable oil.

V. POLICY

Preferably, it should be the policy of food processors to identify their food products as *kosher* whenever appropriate and possible, and to have these products and the plants in which they are produced certified as *kosher* by a qualified *orthodox* rabbi or rabbinical organization.

VI. CERTIFICATION OF NEW PRODUCTS

1. When a new product is still in the concept stage, a marketing decision should be made by the manufacturer as to whether it should be a *kosher* product.
2. If yes, the product development personnel should prepare ingredient specifications calling for *kosher* ingredients and a process should be developed which is also *kosher*.
3. Before labels for the product are approved, (in which the *kashrus* symbol would be incorporated), the *orthodox* rabbi should be contacted and given full particulars as to the formula, the source and nature of the ingredients, and the location and nature of the processing equipment. If these meet with his approval, permission is granted to use the *kashrus* symbol on the label of the packages.
4. The *orthodox* rabbi will usually want to be present at the first production run, to personally verify that the ingredients and equipment are *kosher*.