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HEARING BEFORE THE SUBCOMMITTEE ON PUBLIC HEALTH AND SAFETY OF THE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE HOUSE OF REPRESENTATIVES

EIGHTY-EIGHTH CONGRESS
SECOND SESSION

ON

H.R. 4731

A BILL TO AMEND SECTION 402(d) OF THE FEDERAL
FOOD, DRUG, AND COSMETIC ACT

APRIL 28, 1964

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Committee on Interstate and Foreign Commerce



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CONTENTS

	Page
Text of H.R. 4731.....	1
Reports of—	
Budget Bureau.....	1
Health, Education, and Welfare.....	2
Statement of—	
Ellenbogen, Theodore, Counsel, HEW.....	3
Harvey, John L., Deputy Commissioner, Food and Drug Administration, HEW.....	3
Heide, Andrew H., vice president, National Confectioners Association.....	13
Communications submitted by—	
Gudeman, Edward, Under Secretary of Commerce, letter dated March 2, 1962.....	18
Hoover, William J., administrative vice president, Corn Industries Research Foundation, Inc., letter dated April 27, 1964.....	25

CONTENTS

1. Introduction 1

2. The History of the 10

3. The Development of the 20

4. The Current Status of the 30

5. The Future of the 40

6. The Role of the 50

7. The Importance of the 60

8. The Conclusion 70

USE OF ADDITIVES IN CONFECTIONERY

TUESDAY, APRIL 28, 1964

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON PUBLIC HEALTH
AND SAFETY OF THE COMMITTEE ON
INTERSTATE AND FOREIGN COMMERCE,
Washington, D.C.

The subcommittee met at 10 a.m., pursuant to call, in room 1334, Longworth Building, Hon. Kenneth A. Roberts (chairman of the subcommittee) presiding.

Mr. ROBERTS. The subcommittee will please be in order.

The hearings today are on H.R. 4731, a bill to amend section 402(d) of the Federal Food, Drug, and Cosmetic Act, introduced by our colleague on the committee, Mr. Macdonald.

Under existing law, confectionery is considered per se adulterated if it bears or contains certain nonnutritive articles or substances. The bill would repeal these automatic features of the law, while leaving intact the provisions of the law prohibiting economic adulteration of foods and section 401, which authorizes the establishment of definitions and standards of identity for food.

At this point in the record there will be inserted the text of the bill and the agencies reports thereon.

(The bill and reports referred to follow:)

[H.R. 4731, 88th Cong., 1st sess.]

A BILL To amend section 402(d) of the Federal Food, Drug, and Cosmetic Act

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That section 402(d) of the Federal Food, Drug, and Cosmetic Act, as amended, is hereby amended to read as follows:

"(d) If it is confectionery, and it bears or contains—

"any alcohol other than not to exceed one-half of 1 per centum by volume derived solely from the use of flavoring extracts."

EXECUTIVE OFFICE OF THE PRESIDENT,
BUREAU OF THE BUDGET,
Washington, D.C., April 27, 1964.

HON. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This is in response to your request of March 20, 1963, for the views of the Bureau of the Budget on H.R. 4731, a bill to amend section 402(d) of the Federal Food, Drug, and Cosmetic Act.

In his report to you on this bill, the Secretary of Health, Education, and Welfare recommends against enactment of the bill in its present form and suggested certain changes in the proposed amendment. The Bureau of the Budget concurs in the views expressed by the Department of Health, Education, and Welfare and, accordingly, does not favor enactment of H.R. 4731 in its present

form. However, the Bureau would have no objection to the enactment of this bill if the changes recommended by the Secretary were incorporated in the legislation.

Sincerely yours,

PHILLIP S. HUGHES,
Assistant Director for Legislative Reference.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
September 24, 1963.

HON. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This letter is in response to your request of March 20, 1963, for a report on H.R. 4731, a bill to amend section 402(d) of the Federal Food, Drug, and Cosmetic Act.

The present section 402(d) of the act reads as follows:

"(d) If it is confectionery, and it bears or contains any alcohol or nonnutritive article or substance except authorized coloring, harmless flavoring, harmless resinous glaze not in excess of four-tenths of 1 per centum, natural gum, and pectin: *Provided*, That this paragraph shall not apply to any confectionery by reason of its containing less than one-half of 1 per centum by volume of alcohol derived solely from the use of flavoring extracts, or to any chewing gum by reason of its containing harmless nonnutritive masticatory substances."

The bill would amend this subsection to read as follows:

"(d) If it is confectionery, and it bears or contains—
'any alcohol other than not to exceed one-half of 1 per centum by volume derived solely from the use of flavoring extracts.'"

The original prohibition in the Food and Drugs Act of 1906, inserted because of bad practices which had been employed by some members of the confectionery trade prior to that time, considered confectionery to be adulterated "If it contain terra alba, barytes, talc, chrome yellow, or other mineral substance or poisonous color or flavor, or other ingredient deleterious or detrimental to health, or any vinous, malt, or spirituous liquor or compound or narcotic drug." When the 1938 act replaced the old Food and Drugs Act, the prohibition against nonnutritive substances was not only contained but expanded, as above shown, to cover any nonnutritive substances or articles except harmless coloring, harmless flavoring, glaze, and natural gum and pectin. (The Color Additive Amendments of 1960 changed "harmless coloring" to "authorized coloring.")

The law also prohibits confectionery that "bears or contains" trinkets which are not edible.

H.R. 4731 undertakes to relax these requirements of the law. This must be a matter of concern, especially when the articles involved are foods so widely eaten by people of all ages and particularly by children.

The prohibition against nonnutritive articles such as trinkets has been extremely valuable as a public health measure. We have had reports of children who swallowed these trinkets or whose teeth or mouth tissues were injured as a result thereof. Now that these are prohibited from use in confectionery this problem rarely arises.

We have also encountered consignments of candy made with talc and have uniformly proceeded against such lots under the authority of the present section 402(d). The most recent actions in this field, however, have not involved confectionery manufactured in the United States, but rather products offered for entry from other countries. We believe that if H.R. 4731 were enacted in its present form, it would be claimed that this had the effect of legalizing the addition to talc to confectionery in practically any amount short of that which would so change the characteristics of the product that it would no longer appear to be confectionery. It would also be claimed to have legalized the bad practice of adding trinkets.

It is true that the bill would not affect section 402(b) of the act, dealing with "economic adulteration" of all foods, or section 401, authorizing us to establish definitions and standards of identity for food. We believe, however, that the utilization of section 402(b), the so-called "economic adulteration" section, to deal with nonnutritive substances in products of such variable identity as confectionery would be extremely difficult, and there is, in our opinion,

no likelihood that standards of identity could be promulgated with enough alacrity to handle the problem. Indeed, as mentioned previously, the proposed amendment to section 402(d) might even be claimed, and conceivably held, to have legalized use of such nonnutritive ingredients as talc and the trinkets. Thus, we believe that the proposed amendment goes too far.

We therefore recommend against enactment of H.R. 4731 in its present form.

We understand, however, from discussions with spokesmen for the candy industry, that the industry has no desire to thus weaken the present law but, rather, that it desires merely the right to use safe nonnutritive substances in the manufacturing process where the substance serves a useful purpose, such as the use of mineral oil as slab grease. We would not object to an amendment to the present section 402(d) which would merely provide a means whereby the industry may legally employ safe nonnutritive substances having functional value in the production of this class of food. This could be accomplished by adding to the present section 402(d) an additional proviso along the following lines:

“Provided further, That this paragraph shall not apply to a safe nonnutritive substance which is in or on confectionery by reason of its use in the manufacture, packaging, or storage of such confectionery, if such use of the substance (including the amount thereof remaining in or on such confectionery) is in conformity with a regulation issued and in effect under section 409, but no such regulation shall issue unless the Secretary finds that such use has technological value in such manufacture, packaging, or storage and is in accordance with good manufacturing practice. For the purpose of the application of section 409 (b) through (h) of this act to this proviso, such nonnutritive substance shall be deemed to be a ‘food additive’ whether or not it is such within the meaning of section 201(s). As used in this paragraph (d), the term ‘non-nutritive’ refers to a substance or article which, when ingested by man, is not utilized in normal metabolism, or which is inedible.”

Further, as suggested in our report of February 27, 1962, on a predecessor bill (H.R. 3548, 87th Cong.), we believe it desirable to couple such an amendment with the following additional proviso to clarify present law with respect to the marketing of trinkets with confectionery:

“Provided further, That for the purposes of this paragraph a trinket or other article packaged or held in the same container with confectionery shall be deemed to be contained in such confectionery unless such trinket or other article is not physically integrated with or attached to it and is separately and distinctly wrapped.”

We are advised by the Bureau of the Budget that there is no objection to the presentation of this report from the standpoint of the administration's program.

Sincerely,

ANTHONY J. CELEBREZZE,
Secretary.

Mr. ROBERTS. Our first witness today will be Commissioner John L. Harvey, Deputy Commissioner, Food and Drug Administration. He is accompanied by Mr. Ted Ellenbogen, Office of General Counsel. We are glad to have you gentlemen and I am glad, Commissioner, that you are in a little better health than you were the last time I saw you. I know you had quite a hard time. We are real happy that you are all right now.

STATEMENT OF JOHN L. HARVEY, DEPUTY COMMISSIONER, FOOD AND DRUG ADMINISTRATION; ACCOMPANIED BY THEODORE ELLENBOGEN, OFFICE OF GENERAL COUNSEL, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, WASHINGTON, D.C.

Mr. HARVEY. Thank you very much. Mr. Chairman, I think I will be around for a while yet.

Mr. ROBERTS. Fine. We hope so.

Mr. HARVEY. Mr. Chairman and gentlemen, we are grateful for the opportunity to appear before your committee today to discuss H.R.

4731, a bill to amend section 402(d) of the Federal Food, Drug, and Cosmetic Act.

To discuss the effect that passage of this bill would have upon the consuming public, I should touch briefly upon the history of that portion of the present law.

Prohibitions against the use of certain nonnutritive substances in confectionery have been a part of our national food and drug law for almost 60 years. Such prohibitions in the original Food and Drugs Act of 1906 were enacted because of various harmful manufacturing practices then employed by some firms in the confectionery industry. That act deemed a confectionery to be adulterated—

If it contain terra alba, barytes, talc, chrome yellow, or other mineral substance or poisonous color or flavor, or other ingredient deleterious or detrimental to health, or any vinous, malt, or spiritous liquor or compound or narcotic drug.

When the 1938 act replaced the old Food and Drugs Act, the prohibition against nonnutritive substances was continued and expanded to cover any nonnutritive substances or articles except harmless coloring, harmless flavoring, glaze, and natural gum and pectin.

Later, the Color Additive Amendments of 1960 changed "harmless coloring" to read "authorized coloring."

The present law on the subject, which is incorporated into the Federal Food, Drug, and Cosmetic Act as section 402(d), classifies a food as adulterated—

(d) If it is confectionery, and it bears or contains any alcohol or nonnutritive article or substance except authorized coloring, harmless flavoring, harmless resinous glaze not in excess of four-tenths of 1 per centum, natural gum, and pectin: *Provided*, That this paragraph shall not apply to any confectionery by reason of its containing less than one-half of 1 per centum by volume of alcohol derived solely from the use of flavoring extracts, or to any chewing gum by reason of its containing harmless nonnutritive masticatory substances.

The law also prohibits confectionery that "bears or contains" inedible trinkets or toys.

H.R. 4731 would amend section 402(d) to read:

(d) If it is a confectionery, and it bears or contains any alcohol other than not to exceed one-half of 1 per centum by volume derived solely from the use of flavoring extracts.

This would have the effect of relaxing the high standards set by the present law. The types of food here involved are consumed by virtually every person in this country but particularly by children and teenagers.

The exclusion from confectionery of nonnutritive articles such as trinkets and toys has been extremely valuable as a preventive public health measure. We have had reports of children who have swallowed these articles or who have suffered damage to their teeth or oral tissues when accidentally biting into such trinkets or toys.

We have also encountered consignments of candy made with talc and have consistently proceeded against such shipments under the authority of the present section 402(d). The more recent actions in this area, however, have not involved products of domestic confectionery manufacturers, but rather products offered for entry from foreign ports.

We believe that if H.R. 4731 were enacted in its present form, it would be claimed that this had the effect of legalizing the addition

of talc to confectionery in practically any amount not sufficient to change the character of the product to something other than confectionery.

Representatives of industry, however, have told us that their purpose in proposing this revision to the present law is not to enable them to manufacture candy with objectionable substances such as talc, but rather to permit producers to obtain the advantages of new technological developments—emulsifiers, softeners, and lubricants, for example—which might make better candies with better keeping quality, but which are currently prohibited because they are nonnutritive.

Perhaps domestic manufacturers would not make any claims as to the permissibility of including ingredients such as talc, but foreign producers and domestic importers might since this ingredient has been used in foreign confectionery more recently. It would also be claimed by some to have legalized the dangerous practice of adding toys and trinkets to candy.

It is true that the bill would not affect section 402(b) of the act, which deals with adulteration of foods by economic debasement, or section 401, authorizing the Secretary to establish definitions and standards of identity for food.

But we believe that the utilization of section 402(b), the "economic adulteration" section, to deal with nonnutritive substances in products of such variable identity as confectionery would be extremely difficult. We also believe that there is virtually no likelihood that standards of identity could be promulgated with sufficient speed to deal with the problem.

Indeed, as mentioned previously, the bill, if enacted, might even be claimed, and conceivably held, to have legalized the use of such nonnutritive ingredients as talc and trinkets. Thus, we believe that the proposed amendment goes too far.

Therefore, Mr. Chairman, as noted in our Department's report on the bill dated September 24, 1963, we must recommend against enactment of H.R. 4731 in its present form.

However, as noted earlier, we understand that the confectionery industry has no desire to weaken the present law, but merely seeks the right to utilize safe nonnutritive substances in manufacturing processes where such substances would serve a useful purpose.

We would not object to an amendment to section 402(d) which would merely provide a means whereby the industry may legally employ safe nonnutritive substances having functional value in the production of this class of food. This could be accomplished by adding to the present section an additional proviso along the following lines:

Provided further, That this paragraph shall not apply to a safe nonnutritive substance which is in or on confectionery by reason of its use in the manufacture, packaging, or storage of such confectionery, if such use of the substance (including the amount thereof remaining in or on such confectionery) is in conformity with a regulation issued and in effect under section 409, but no such regulation shall issue unless the Secretary finds that such use has technological value in such manufacture, packaging, or storage and is in accordance with good manufacturing practice. For the purpose of the application of section 409(b) through (h) of this Act to this proviso, such nonnutritive substance shall be deemed to be a "food additive" whether or not it is such within the meaning of section 201(s). As used in this paragraph (d), the term "nonnutritive" refers to a substance or article which, when ingested by man, is not utilized in normal metabolism, or which is inedible.

Further, as suggested in our report on the bill, we believe it desirable to couple such an amendment with the following additional proviso to clarify present law with respect to the marketing of trinkets with confectionery:

Provided further, That for the purposes of this paragraph a trinket or other article packaged or held in the same container with confectionery shall be deemed to be contained in such confectionery unless such trinket or other article is not physically integrated with or attached to it and is separately and distinctly wrapped.

Thank you, Mr. Chairman, for affording us the opportunity to present this statement of our position on H.R. 4731. We will of course do our best to answer questions that the committee may have.

Mr. ROBERTS. Thank you, Commissioner. The bill would, if I understand correctly, allow the use of certain nonnutritive substances that are not permissible under present law. Is that correct?

Mr. HARVEY. That is correct, as I understand it, Mr. Chairman.

Mr. ROBERTS. What would be the types of these substances? I believe you mentioned they would be emulsifiers, softeners, and lubricants. You classified those three I believe.

Mr. HARVEY. That is right, Mr. Chairman.

Mr. ROBERTS. Maybe I should save this for the industry, but I know you have a wide experience in this field. What would be an example, if you have one that comes to mind, of one of these substances that is nonnutritive and safe but is not permitted under present law?

Mr. HARVEY. One that my colleagues have suggested to me Mr. Chairman, is mineral oil slag grease which is applied to the slabs of tabletops upon which confectionery is handled.

Mr. ROBERTS. What effect would that have? Does it make it easier to work the confectionery? Is that the purpose of it?

Mr. HARVEY. Yes.

Mr. ROBERTS. Are most of the candies—I say candies because that is the first one that comes to my mind, but I am sure there are other types—made with the use of a great deal of machinery and equipment? I mean is there much actual manual handling of the confectionery, or is most of it handled by mixture, and metallic containers, and that sort of device?

Mr. HARVEY. Most of the manufacturing processes are handled by machinery, yes.

Mr. ROBERTS. Are the standards of manufacture in our country in your opinion in what we would call good sanitary conditions according to the information that you have available at this time?

Mr. HARVEY. Yes. Yes, generally, the candy factories are clean and well operated.

Mr. ROBERTS. Do you have any way of inspecting the product of foreign manufacturers before it gets to this country?

Mr. HARVEY. No, sir; we do not.

Mr. ROBERTS. In other words, your only chance at it is after it is ready for consumption by the customers here?

Mr. HARVEY. That is certainly true as a routine proposition. I do recall a certain instance in which during wartime, when we were receiving great quantities of candy from a nearby country because of shortages of sugar here, restrictions on the use of sugar, we encountered such weird material in the laboratories that we made arrangements

through the State Department to have some of the attachés visit some of the foreign candy manufacturers.

Of course that was with the consent and on the invitation, you might say, of the foreign manufacturers. However, aside from that particular situation we have no facility for any foreign inspection and no authority.

Mr. ROBERTS. I was under the impression that in connection with the Drug Amendments Act of 1962 we incorporated a new section on foreign foods and drugs.

Mr. HARVEY. There is a provision in the 1962 amendments relating exclusively to drugs which provides in relation to the registration of foreign drug manufacturers that registration must be made contingent upon the Secretary having a suitable facility and opportunity for inspection either by arrangement with the foreign government or otherwise.

This is exclusively with drugs and it presents a fairly elaborate problem and it has not been implemented yet.

Mr. ROBERTS. I don't know how you feel about it, but it seems to me that we ought to explore this somewhat, and perhaps we need to give you more authority over foreign imports in this field, in the whole food field, as a matter of fact, because a lot of it is coming in here in competition with our own manufacturers.

It seems foolish to me to require high standards for our own people and not do that for things that are coming in from other countries.

Mr. HARVEY. I can certainly comment and say that, without an opportunity to inspect the manufacturer and the raw materials, we cannot appraise and evaluate a product in the same way as we can when we have access to the factory.

We, of course, can subject importations of candy and all other foods to a sample analysis at the time they are offered for entry within the limits of our resources, and we do.

We do examine foreign candy to a significant extent I think and we have encountered a number of situations, one of which I recall where they used ordinary house paint as a coloring material in candy.

Several years ago—I think about 4 years ago—much to my surprise, in one of the ordinarily high-grade English taffies we encountered a considerable amount of talc, the common filler that was used years ago, so that it is quite true that the opportunity to investigate, to evaluate, food products generally that we have in this country does not apply to foreign countries.

I recognize, of course, that it would involve a considerable amount of exploration. Certainly the State Department has a big interest in the matter, and it would involve international agreements I believe to work, but I answer your question by saying that the same opportunity to evaluate the food products that we have here through inspection and analysis and investigation of raw materials and sources we do not have in foreign production.

Mr. ROBERTS. Thank you, Mr. Commissioner. Just one other question and I am through. With the amendments you suggested and the proviso that you mentioned would you go along with the bill H.R. 4371?

Mr. HARVEY. Yes, sir.

Mr. ROBERTS. That is all I have. The gentleman from Minnesota.

Mr. NELSEN. Thank you, Mr. Chairman. I notice this paragraph on page 4:

However, as noted earlier, we understand that the confectionery industry has no desire to weaken the present law, but merely seeks the right to utilize safe nonnutritive substances in manufacturing processes where such substance would serve a useful purpose.

I take it from that language that you do agree that there are some revisions that could be usefully made to the candy manufacturing industry by some relaxation of the present law.

Is that true?

Mr. HARVEY. Yes, sir; I believe so.

Mr. NELSEN. You further state that the proposed amendment goes too far relative to trinkets. Has there not been some discussion between the industry and the Food and Drug Administration relative to the trinkets provision with the idea that they would be perfectly willing to make it clear in the language of this bill?

Has there not been some correspondence going back and forth?

Mr. HARVEY. I do understand that we can meet on common ground with the industry so far as the trinkets are concerned. I would comment that by suggesting that the proposed bill goes too far, I intended it to apply not alone to trinkets, but to the other provisions, relaxing of nonnutritive substances generally.

Quite frankly, I think we would have a tremendous amount of difficulty with the imported products if we have the type of relaxation that is suggested by this bill. There have been at least 16 shipments of confectionery that we stopped at the port of New York in the last 5 years containing various nonnutritive substances.

Mr. NELSEN. This has been covered to some degree by the chairman's questioning. How do you check thoroughly on imported products?

Of course, you would have to analyze the product to determine what is in it. It would be very difficult, I would presume, to check the foreign manufacturer's product, would it not, much more difficult, as you have mentioned earlier, than checking our own manufacturers?

Mr. HARVEY. This is true, and candy of course comes in almost an infinite variety and it presents at least time-consuming and troublesome problems that you can't get in a shipment of canned beans, for example.

Mr. NELSEN. Thank you. It has been my information that some of the restrictions under the present law have made it very difficult for a candy manufacturer. For example, you mentioned mineral oil. I understand in the manufacturing process unless something is put on the table the product will stick to the table.

Mr. HARVEY. That is right.

Mr. NELSEN. And to use a mineral oil under the terms of the bill would be illegal, would it not?

Mr. HARVEY. If it is introduced into the candy, yes.

Mr. NELSEN. And I presume it would be if it is on the table.

Mr. HARVEY. I think it is inescapable to a degree; yes, sir.

Mr. NELSEN. It is also my understanding that many nonnutritive additives are permitted, for example, in a baby food that would not be permitted in candy. Is that true?

Mr. HARVEY. Frankly, I am unaware of any permissive use of non-nutritives in baby food. There may be some, but I don't recall. Do you? I think you have chosen an example where I would be fairly safe in saying "no" to that question.

Mr. NELSEN. I was wondering about chewing gum, for example. Is chewing gum nutritive?

Mr. HARVEY. No. Chewing gum by its nature is nutritive only to the extent of the sugar and slight amount of flavor that is derived from it. Also it isn't swallowed, except the soluble parts. At least it isn't intended to be swallowed.

Mr. NELSEN. Has the proposed amendment that you suggest here been discussed at all with the industry that is under consideration?

Mr. HARVEY. Yes, sir.

Mr. NELSEN. Mr. Chairman, at this time I don't believe I have any further questions, but I do hope that at some later date, if we get to discussing this proposed amendment, that we might be in the position to ask further questions of the Department.

We certainly want to do everything we can to be sure that no mistakes are made in this very important field.

Mr. ROBERTS. The Department is always willing to come up so we have no trouble with that.

Mr. O'Brien.

Mr. O'BRIEN. Mr. Chairman, I am really touched by the concern for the children in this matter. They do eat a great deal of candy from my observation. I have seven grandchildren. They also eat a great deal of cake, cookies, ice cream, soft drinks, and I will skip baby foods. I would say the quantity consumed of those articles is much greater than the quantity of candy consumed.

Why is candy singled out?

Mr. HARVEY. I would say first of all that the practices that did prevail at the time of the enactment of the law in 1906 focused attention on candy as a children's food that needed correction. Through the years I am sure that candy has improved a great deal, at least in this country, both in the law and under good conscience.

So far as the soft drinks are concerned, the only nonnutritive substances that I am familiar with that are used in those are the specially identified saccharin or sucro-sweetened products which are clearly identified and which a great deal of experimentation has shown to be harmless.

Mr. O'BRIEN. You mentioned that the situation was pretty bad in the candy industry some years ago.

Mr. HARVEY. That is right.

Mr. O'BRIEN. So you put in a strong law.

Mr. HARVEY. That is right.

Mr. O'BRIEN. And after 60 years of probation you are unwilling to concede a thing to the candy industry? They have improved. You said so.

Mr. HARVEY. Yes, I have a great deal of confidence in the domestic candy industry and very little in the foreign, to be frank about it.

Mr. O'BRIEN. Why should the American products be punished because in some way our Government is unable to control imports?

Mr. HARVEY. I don't believe that the proposal that the Department is offering here is in the nature of punishment at all. I think that in

any instance where the manufacturer can show it is a safe and useful nonnutritive addition to his candy and it would be a desirable thing, he can do so.

Mr. O'BRIEN. Are people who use additives in other foods required to produce that kind of proof? Why candy alone?

Mr. HARVEY. Yes, to answer your question, Mr. O'Brien, in the additive field generally they are required to produce this.

Mr. O'BRIEN. Not in as many specific instances as the candy industry.

Mr. HARVEY. Well, if the substance is in fact a food additive in every instance its use has to be justified by regulation.

Mr. O'BRIEN. Then you have to justify it a second time because it goes into candy; isn't that correct?

Mr. HARVEY. Well, one justification would be sufficient. If it were justified for soft drinks, for example, any additive would have to be justified if used in some other food.

Mr. O'BRIEN. I have no desire to poison children, but is the administration of your Department as concerned as you appear to be by your testimony here today, or is there a possibility that, having had on the books for a number of years a very stringent law, needed and desirable at the time it was enacted, you don't want to be put in the position if some child gets a bellyache from a candy bar of saying, "Well, we let down the bars and we are responsible so let's keep this old law on the books." Is that possible?

Mr. HARVEY. I wouldn't deny that we wouldn't want to be put in that position, Mr. O'Brien, but I don't think that this is the root of the Department's point of view.

Mr. O'BRIEN. I can't understand any other reason for it. I believe the American public is entitled to a tremendous amount of protection in what it consumes, what it eats, and that includes candy as well as spinach, but I can't see why one product, one product alone, should be singled out for very special protection.

You have mentioned trinkets. That is a very minor thing. The injection of the trinkets argument into this situation indicates to me that the Department is reaching very far afield to prove a point that doesn't exist.

As I say, I don't want children in this country poisoned but I think that they are entitled to the same protection in baby foods or cake or candy or cookies and that one industry not singled out as the villain in the piece.

Mr. HARVEY. Mr. O'Brien, on the trinkets, the Department's interest in dragging this in, to use that phrase, arises out of the fact that under the law as it is now written with regard to trinkets we have an adverse decision in the court of appeals over a district decision which complicates the enforcement of the law with regard to that particular type of adulteration.

We felt that this ought to be clarified, and so far as I am aware there is no serious objection to the straightening out on the part of the candy industry.

Mr. O'BRIEN. That is my understanding too, so it boils down to this very simple fact, as I see it: That the children of this country need a protection with regard to candy that is not given to them in any other product they consume; is that correct?

Mr. HARVEY. I think that is correct.

Mr. O'BRIEN. Thank you, Mr. Chairman.

Mr. ROBERTS. Thank you, Mr. O'Brien. Mr. Rogers.

Mr. ROGERS of Florida. I am sorry I was just a little late and didn't have time to read your full statement. Do I understand that you treat the confectionery industry differently than you do the other industries that use food additives?

Mr. HARVEY. The statute, Mr. Rogers, both the old 1906 law and the 1938 law, has a section, a clause, on confectionery which is designed to prohibit most of the nonnutritive substances that may be used in candy, to specify those that can and limit them.

Mr. ROGERS of Florida. Is it true that that is a different treatment than for other food industries, industries that use these same substances?

Mr. HARVEY. In the sense that nonnutritive substances are not statutorily prohibited in other foods; yes.

Mr. ROGERS of Florida. Why should it be here then?

Mr. HARVEY. Among the reasons is the fact that nonnutritive substances have been rather extensively used in candies and, as I commented earlier, to a considerable extent are now in use particularly in foreign countries.

Mr. ROGERS of Florida. This could be true I suppose with many other industries, couldn't it? Do you check all the foreign goods that come in? Do they always use the same thing as our domestic industry?

Mr. HARVEY. Not invariably, except where there are standards that require them to do so.

Mr. ROGERS of Florida. Well, if it is permitted in food that our people are going to consume, the children and the old people too, in other foods, what is the distinction here?

Why should just candy be set apart?

Mr. HARVEY. The first and primary reason is because the candy is consumed largely by children.

Mr. ROGERS of Florida. So is bread and so is everything else. I don't think that is a good argument. It is either safe or it isn't.

Mr. HARVEY. Our proposal I think, Mr. Rogers, with regard to this bill would have the effect of putting all the foods on the same basis.

Mr. ROGERS of Florida. What is that? How would you do that?

Mr. HARVEY. We have merely suggested as to the nonnutritive substances, instead of being prohibited, that the use be authorized after the proposal is considered and a showing is made that they serve some useful and substantial purpose and are safe, which is true of food additives generally.

Mr. ROGERS of Florida. Would that apply to all food additives in all other industries then?

Mr. HARVEY. The food additive law of course already applies to all other industries.

Mr. ROGERS of Florida. I am saying your proposal. Would it apply to all others, or just the confectionery industry.

Mr. HARVEY. This proposal would apply only to the confectionery.

Mr. ROGERS of Florida. Why don't you want to put them along with every other industry. Why shouldn't they be treated the same as any other industry? Is there any reason for it?

Mr. HARVEY. We think so; yes.

Mr. ROGERS of Florida. What is the difference?

Mr. HARVEY. Mr. Rogers, there are two sides to this. One of our problems, if we enact a law such as is proposed here, would be dealing with foreign importations of candy which, as I pointed out earlier, are presently the source of nonnutritive substances that are causing us considerable trouble.

Mr. ROGERS of Florida. Suppose we write into the law then that no foreign candy can be imported with these substances. Would that please you then? Suppose we put in a provision saying nothing can be brought in with that?

Mr. HARVEY. But you make a different role for the imported article than we have for the domestic article.

Mr. ROGERS of Florida. Well, you say that is what is needed. That is your argument. That is not mine. You just said that the only reason you want this is for the foreign candies.

Mr. HARVEY. I didn't intend to say that is the only reason.

Mr. ROGERS of Florida. I don't mean to put words in your mouth. We will rule that out. What are the other reasons?

Mr. HARVEY. You say what are the other reasons?

Mr. ROGERS of Florida. Yes, why you would be opposed to putting the candy industry on the same basis as the other domestic industries.

Mr. HARVEY. I think candy is a product of a special classification of its own and I don't believe that artificial sweeteners, and mineral oil, and things of that kind are proper in candy.

Mr. ROGERS of Florida. Even though it is safe?

Mr. HARVEY. Well, I want to be sure it is safe. It sends us to some other sections of the law.

Mr. ROGERS of Florida. Doesn't the food additive law require safety?

Mr. HARVEY. If it is a food additive.

Mr. ROGERS of Florida. I thought that was what we wrote into the law, as I recall.

Mr. HARVEY. That is right. We are simply proposing here that any nonnutritive substances proposed for use in candy be passed on in the same way that a food additive is.

Mr. ROGERS of Florida. Why differently though? Why don't you treat them all the same? Why do you want to make a distinction?

Mr. HARVEY. I don't exactly see that this is making a distinction.

Mr. ROGERS of Florida. You say you are treating the confectionery industry differently than you are all of the other industries that used food additives. Why don't you have the same ground rules? As long as the food is safe and not harmful why shouldn't the candy industry be treated the same way?

Mr. HARVEY. I think that our proposals, Mr. Rogers, essentially do that.

Mr. ROGERS of Florida. Then you have no objection to treating them the same?

Mr. HARVEY. I have no objection to any additive that goes into a food, whether it is candy or some other product, being treated the same way, that is right.

Mr. ROGERS of Florida. I think that will help the committee then. We can treat them all the same. Thank you.

Mr. ROBERTS. Anything further?

Mr. NELSEN. No more questions.

Mr. ROBERTS. Anything further? Thank you, Mr. Commissioner.

Mr. HARVEY. Thank you, Mr. Chairman and gentlemen.

Mr. ROBERTS. Our next witness will be Mr. Andrew Heide, vice president, National Confectioners Association, and chairman of the association's committee on food and drug administration problems.

STATEMENT OF ANDREW H. HEIDE, VICE PRESIDENT, NATIONAL CONFECTIONERS ASSOCIATION AND CHAIRMAN OF ASSOCIATION'S COMMITTEE ON FOOD AND DRUG ADMINISTRATION PROBLEMS

Mr. HEIDE. Mr. Chairman, my name is Andrew H. Heide. I am president and chairman of the board of Henry Heide, Inc., confectionery manufacturers located in New Brunswick, N.J., and I appear as vice president, as a member of the board of directors, and as chairman of the Committee on Food and Drug Administration Problems of the National Confectioners Association.

This association is a national trade association of confectionery manufacturers located throughout the United States and suppliers of goods and services to the industry. We estimate our manufacturer members produce approximately 85 percent of the confectionery produced in the United States.

This appearance is entered in support of H.R. 4731 which would place confectionery on an equal basis with all other segments of the food industry regarding the use of food additives.

PURPOSE AND NEED FOR H.R. 4731

As I commence my statement, there is one point I want to make absolutely clear to prevent any misunderstanding regarding this proposed legislation.

We are concerned with safe additives and only with safe additives. By safe additives we have reference to additives which the Food and Drug Administration already has declared to be safe for unrestricted use or safe for use within prescribed limits.

Also, we are concerned with additives which the Food and Drug Administration in the future may approve for unrestricted or limited use by food industries in general. This legislation does not pertain, or would not have application, to any additive which the Food and Drug Administration either has not declared to be safe for unrestricted use or safe for use within prescribed limits.

Under existing law unless a specific additive is nutritive, the Food and Drug Administration may not authorize its use in confectionery even though it is absolutely safe and its usage may be authorized for all other segments of the food industry.

We have two basic reasons for strongly advocating the legislation. One, and admittedly this is a heavy point with us, is that existing law unfairly, unnecessarily, and without any useful purpose whatsoever discriminates against the confectionery industry. As hard as it is to believe, this is all there is to it.

Admittedly, a complexity of laws has brought about the inequitable situation which I shall explain. Nevertheless as a result of the appli-

cation of the various provisions of the food and drug law, the confectionery industry, and only the confectionery industry, may not use nonnutritive substances which other segments of the food industry may use.

Aside from the matter of discrimination without a basis, section 402(d) of the Federal Food, Drug, and Cosmetic Act has a very direct application to our business operations. As we all know, in today's world of chemistry new additives are continually being developed—additives which will increase shelf life and impart desirable qualities to the product from the standpoint of taste, texture and flavor enhancement—that is, preservatives and emulsifiers of all kinds.

Properly the food additives amendment requires the safety of such additives to be established to the satisfaction of the Food and Drug Administration.

However, after the Food and Drug Administration establishes the safety of such additives, either for unrestricted use or for use within prescribed limits, such additives may be used by the canning, frozen food, baking, bottling, and preserving segments of the food industry among others, as well as the baby foods industry.

However, such safe additives may not be used by confectionery manufacturers because of section 402(d) of the Federal Food, Drug, and Cosmetic Act which provides as follows:

A food shall be deemed to be adulterated—

(d) if it is confectionery, and it bears or contains any alcohol or nonnutritive article or substance except authorized coloring, harmless flavoring, harmless resinous glaze not in excess of four-tenths of one per centum, natural gum, and pectin: *Provided*, That this paragraph shall not apply to any confectionery by reason of its containing less than one-half of one per centum by volume of alcohol derived solely from the use of flavoring extracts, or to any chewing gum by reason of its containing harmless nonnutritive masticatory substances.

H.R. 4731 would amend section 402(d) to read as follows:

(d) If it is confectionery, and it bears or contains—"any alcohol other than not to exceed one-half of one per centum by volume derived solely from the use of flavoring extracts."

Let me provide an illustration to indicate the problem this matter presents for our industry. Let us assume a candy manufacturer is in need of an additive to impart some special quality to one of his products. He consults his technical personnel who in turn consult with some of the Nation's leading chemical companies who manufacture additives for use by the food industry.

After study the candy manufacturer may be advised that his supplier has the very additive which will serve his purpose which has been declared to be safe and which may be used by other segments of the food industry. Then the manufacturer must ask the question which the law requires, but which serves no useful purpose—that is, is the particular additive nutritive?

If, fortunately, the additive happens to be nutritive, then all is fine. If it happens that the additive is not nutritive, he cannot use it irrespective of the final qualities and its capacity to impart the qualities which he desires.

Also, there are times when it is not known whether or not the particular additive is nutritive. When this occurs, obviously the particular additive either is not nutritive or is nutritive only to an insignificant extent. From the standpoint of nutrition, such an addi-

tive is virtually worthless, but if there is any nutritive value whatsoever, legally it may be used. To determine this factor, however, considerable technical analysis may be necessary, all of which serves no useful purpose except in connection with the legal requirement.

HISTORY OF DEVELOPMENT OF THE CURRENT SITUATION

Many years ago, before the turn of the century, harmful additives were being used by some candy manufacturers. This became a concern of legitimate candy manufacturers. In fact, when the National Confectioners Association was organized in 1883, an important objective was to advocate Federal legislation which would prevent the manufacture and shipment in interstate commerce of confectionery containing harmful additives.

Apparently at that time the most meaningful index of wholesomeness was nutritiveness and legislation was enacted which has been carried forward in subsequent food and drug laws including the present law which requires, with certain minor exceptions, that all additives used in confectionery must be nutritive.

This provision of law served a useful purpose for many years. However, as new additives were developed which could be used by all other segments of the food industry, the language served to place a severe restriction on confectionery manufacturers.

Accordingly, we discussed the matter with food and drug officials about 10 years ago to determine the FDA viewpoint regarding possible amendment. The informal opinion of FDA officials was that the Department would oppose any relaxation of section 402(d) at that time. They stated they would be willing to consider elimination of the discriminatory provision regarding nonnutritive substances in confectionery if and when a broad food additives amendment should be enacted requiring pretesting to assure the safety of all additives used in all foods.

They made it clear that the position which they took at that time did not mean a different position would be taken at such time as an overall food additives amendment should be enacted. They merely stated they would be willing to consider the problem at such time. They explained and we understood their position that they did not feel they could consider easing section 402(d) control over the confectionery manufacturers until they should have adequate means of control over all segments of the food industry to assure the safety of all additives used in all foods.

Although this position made it difficult for confectionery manufacturers at the time, we understood and readily accepted the FDA position.

Several years later, after the food additives amendment became law, we returned to the Department and renewed our discussions. At first we were encouraged and were hopeful that inasmuch as FDA had authority to make sure all additives used in all foods were safe the Department would cooperate with the industry in obtaining amendment to section 402(d) so confectionery manufacturers might use the same safe nonnutritive substances which other segments of the food industry may use.

However, as you are aware, the Food and Drug Administration has expressed opposition to H.R. 4731.

COMMENTS ON FDA OBJECTIONS TO H.R. 4731

For ready reference, attached to my prepared statement is a copy of the letter from Health, Education, and Welfare Secretary, the Honorable Anthony J. Celebrezze, to Chairman Oren Harris, dated September 24, 1963, expressing the objections of the Department to H.R. 4731.

(NOTE.—The letter referred to appears on p. 2.)

Mr. HEIDE. The letter makes reference to the Food and Drugs Act of 1906 and subsequent acts which expand section 402(d) and then criticize H.R. 4731 which would relax section 402(d) and points out the heavy consumption of confectionery by children.

Reference to the 1906 and subsequent acts is appropriate, however, as presented it is a watch without a mainspring. The mainspring is the Food Additives Amendment of 1958. If the food additives amendment had not been enacted, the comments would have been appropriate.

Prior to the enactment of the food additives amendment, the principal legal deterrent to the use of harmful additives in confectionery was section 402(d). The food additives amendment, however, prevents the use of any harmful additives in any food and the inclusion of harmful additives in confectionery still would be prohibited even if H.R. 4731 were enacted.

Instead of enacting the food additives amendment, Congress could have expanded the nonnutritive principle of section 402(d) to all other food products in addition to confectionery. Whereas nutritiveness may have been the best index to assure wholesomeness at the beginning of the 20th century, unquestionably it is not the best index to assure wholesomeness at the middle of the 20th century.

We think Congress wisely decided to establish a requirement of proof of safety instead of a requirement of nutritiveness in enacting the overall food additives amendment; otherwise other segments of the food industry would be in the same position in which confectionery manufacturers have been relegated; namely, prohibition against the use of desirable and harmless nonnutritive substances.

The Department's letter makes an issue of talc. To us, this is nothing but a strawman. If talc is harmful, the food additives amendment gives the Food and Drug Administration full power to restrict its use not only by the confectionery industry but by all other food industries and we see no reason for a determination of the authorized usage of any additive to be different in the case of confectionery than in the case of any other food product.

Another point, which the Department raised which we feel is just as empty as the others, suggests that standards of identity would be necessary for confectionery in the event section 402(d) were modified in accordance with the provisions of H.R. 4731.

The Department states that such standards would be difficult to develop in the case of confectionery. It is true there are standards of identity covering a number of food commodities, but there are also many more food commodities which are not covered by standards of identity and which need not be so controlled, including confectionery.

Finally, the Department indicates it would be agreeable to amending section 402(d) to permit the confectionery industry to use safe nonnutritive substances if, when, and to the extent FDA should approve such usage by individual regulation in each instance.

Mr. Chairman, we respectfully ask, Why should we be required to have the permission of FDA to use an additive which FDA has already certified as being safe for use by all other segments of the food industry?

The suggested language itself, which the Department advocates, indicates that the Department would approve the usage of such non-nutritive substances only when it makes a finding "that such use has technological value in such manufacture, packaging, or storing * * *." This is a principle which was advocated but rejected by Congress in enactment of the food additives amendment.

We suggest that technological advancement and improvement today would be far below its present high standard if a Government agency in each instance had to be convinced of the technological value of a particular additive. This is the responsibility of the manufacturer in our private enterprise system.

Rightfully it is the responsibility of the Food and Drug Administration to make sure that the use of a particular additive is safe, but its technological value should be determined by the manufacturer without reference to the Food and Drug Administration. Under existing law, the confectionery industry is treated as a second-class citizen and the amendment suggested by the Department would continue such treatment.

We have an illustration which we feel is particularly applicable to the situation. A group of citizens are standing on the street corner waiting for a traffic light to turn green. After the traffic light turns green, all of the citizens except one commence to cross the street. However, this particular citizen must first obtain permission from the policeman on the corner before he may cross on the green light.

The Food and Drug Administration in approving the safety of food additives gives a green light to all other segments of the food industry, from canning and freezing manufacturers to baby food manufacturers, but insists that confectionery manufacturers must have permission to proceed on the green light. We believe that the elected representatives of the people, our Congress, will not permit such action.

At this point let it be emphasized that we approve and respect most of the activities of the Food and Drug Administration including inspections to insure plant sanitation and the requirements for the establishment of the safety of all additives used in all foods.

In seeking to continue to impose on the confectionery industry a requirement that its members obtain the permission of the Food and Drug Administration for the use of safe additives, we contend the Department has overstepped its bounds inasmuch as the food additives amendment bestows on the Department all of the power it needs.

DEPARTMENT OF COMMERCE POSITION

Although, apparently, the Department of Commerce was not requested to comment on H.R. 4731, the Department was invited to comment on a similar bill in the preceding Congress—H.R. 3548. For

ready reference I am attaching to my prepared statement a copy of a letter from the Honorable Edward Gudeman, the then Under Secretary of Commerce, addressed to Chairman Oren Harris dated March 2, 1962, in which the Department states its support of the bill. You will note one paragraph in the letter reads as follows:

One of the objectives of H.R. 3548 is to remove discrimination against one of the food industries (confectionery) arising from the situation in which no other food industries are prohibited from using harmless nonnutritive ingredients, as is the confectionery industry under the present section 402(d). To the extent that H.R. 3548 would accomplish this purpose, the Department of Commerce favors the bill.

CONCLUSION

Our position simply is that now that there is a broad statute requiring thorough pretesting of all food additives to assure safety before they may be used in any foods, that there is no reason why confectionery manufacturers should continue to be discriminated against and required to submit to a different and more exacting but also meaningless standard to which no other segment of the food industry is subjected.

(The Department of Commerce report referred to follows:)

THE SECRETARY OF COMMERCE,
Washington, D.C., March 2, 1962.

HON. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This letter is in further reply to your request for the views of this Department with respect to H.R. 3548, a bill to amend section 402(d) of the Federal Food, Drug, and Cosmetic Act.

Chapter III of the Federal Food, Drug, and Cosmetic Act prohibits and provides penalties for adulteration of food in interstate commerce. The present section 402(d) of the act defines what constitutes adulterated confectionery as that which contains any alcohol (except less than one-half of 1 percent originating from use of flavoring extracts) or any nonnutritive article or substance (except less than four-tenths of 1 percent of a harmless coloring, flavoring, resinous glass) and except natural gum and pectin.

Enactment of H.R. 3548 would remove from the present provisions "any nonnutritive substance" such as "harmless coloring, flavoring, resinous glass," as adulterants in confectionery, and would add the requirement that any nonnutritive object or trinket must be separately wrapped.

One of the objectives of H.R. 3548 is to remove discrimination against one of the food industries (confectionery) arising from the situation in which no other food industries are prohibited from using harmless nonnutritive ingredients, as is the confectionery industry under the present section 402(d). To the extent that H.R. 3548 would accomplish this purpose, the Department of Commerce favors the bill.

This Department also believes that the present prohibition against alcohol should be continued, as proposed in H.R. 3548. With respect to the proposed subsection (2) of section 402(d), it appears probable that new language may be proposed and we make no comment on this subsection at this time.

The Bureau of the Budget advised there would be no objection to the submission of this report from the standpoint of the administration's program.

Sincerely yours,

EDWARD GUEDEMAN,
Under Secretary of Commerce.

Mr. ROBERTS. Thank you very much for your statement. Have you had an opportunity to review the suggested amendments which the FDA covered in its testimony this morning?

Mr. HEIDE. Yes, sir.

Mr. ROBERTS. What is your opinion of the effect of these amendments?

Mr. HEIDE. Mr. Chairman, we in the confectionery industry feel that it is discriminatory for us to be subjected to any regulation more stringent than those that apply to other segments of the food industry.

The recommendations of the Food and Drug Administration would continue this discrimination. It would still leave us as second-class citizens in the food industry.

If a material is proved to be safe, it is safe regardless of what type of food it is included in. If it is permissible, let us say, to use something in a loaf of bread, which is always referred to as the staff of life—I am sure that more people eat bread than eat candy—I see no reason why we should not be permitted to use it in our industry.

Mr. ROBERTS. Other than the fact that you are certainly opposed to this matter of discrimination as far as your industry is concerned or setting it apart for different treatment than is accorded other segments of the food industry, how does this particular requirement hobble or restrict your industry at the present time?

Mr. HEIDE. Mr. Chairman, there are a number of nonnutritive substances which would enhance the quality of confectionery products which we, under the law, are not permitted to use. There are, as we know today in the scientific world, developments taking place at a much more rapid pace than in times gone by and we know that there will be available to the food industry various types of materials which will improve food products generally.

Should they happen to be nonnutritive, even though it would enable us to produce a better product for the consumer, we would be denied the use of these new commodities as they come on to the market.

Mr. ROBERTS. How does the restriction affect the industry from an economic standpoint?

Mr. HEIDE. The point is a very excellent one and one that I feel should be made as clear as we possibly can make it. There is no economic advantage in what the confectionery industry is asking for here.

The nonnutritive materials that would be incorporated into confectionery products in themselves are such a minute portion of the total mass and in every instance, with very few exceptions, are considerably more expensive than the basic materials used in confectioneries that it doesn't affect us economically in that sense at all.

In other words, we are not seeking to cheapen our products; we are seeking to improve the finished product, so that the consumer will have an even better product than we have been able to furnish up to the present time.

Mr. ROBERTS. Do you sometimes with respect to a soft candy, for instance, have complaints from stores and people who carry the line of candies to the effect that in certain types of weather you get melting and loss of product in that way?

Mr. HEIDE. I believe, Mr. Chairman, what you are referring to does not have a particularly direct bearing on this problem. I think what you are referring to might be the extremes of temperature that would have an adverse effect on confectionery products.

I think we are primarily concerned, first of all, with materials that do enable us to conduct our manufacturing operations more efficiently. There are some nonnutritives that are releasing agents. If you didn't have the use of these materials you would run into all sorts of manu-

facturing difficulties as far as getting the candy to free itself from the mold in which it is cast, or the candy, if it is not treated with a certain kind of a polish, such as a resinous glaze which we are permitted to use under limits, would stick together.

It would be in one large mass in a box. The pieces would not be individually free one from the other, and there are additives that enhance the flavor. There are other materials that would extend the shelf life of a product. Some candies would dry out in a relatively short time.

There are some materials that can be used and should be available to us that would extend the shelf life of a product so that it would keep for a much longer time and be much more palatable to the consumer at the time he purchased it.

Mr. ROBERTS. Mr. O'Brien?

Mr. O'BRIEN. Thank you, Mr. Chairman. You testified for the National Confectioners Association. May I ask what your own company is, sir?

Mr. HEIDE. My company, Mr. O'Brien, is Henry Heide, Inc., of New Brunswick, N. J.

Mr. O'BRIEN. Do you have any particular brand name?

Mr. HEIDE. We sell products which I hope some of you gentlemen might recognize, such as Jujufruits, Jujubes, licorice pastilles, diamond licorice drops. We have been in the confectionery business for 96 years.

Mr. O'BRIEN. The witness for the Department seemed to make three points: One, that rather extraordinary precautions are needed in this field because candy is largely consumed by children, which is a point I am willing to concede, although there is a tremendous consumption by adults, too.

Do you think that argument in and of itself can stand when we don't have the same restrictions with regard to bread?

Mr. HEIDE. No, sir. I think children, if I may just add to the answer, do consume very substantial quantities of ice cream, bottled beverages, soda pop, cookies, and various other forms of sweets, much to our displeasure at times, because they have captured a good share of the children's dollar market and the confectionery industry is fighting hard to hold its place with the children and the money they have to spend.

They ingest tremendous quantities of these other foods and, if it is safe to have product X in a cookie, or a piece of cake, or in a scoop of ice cream, I quite frankly can't understand why it is safe in that form but must be injurious if it is in the form of a candy bar.

Mr. O'BRIEN. The second point was the difficulty of controlling the imported candy which might not be as safe for children or adults as the domestic brands. What about that point?

Mr. HEIDE. I believe that there is a lot to be done in that field and I think this has been explored by our industry with Food and Drug, and we in our industry would like to see, instead of just talking about a very limited number of safe nonnutritives, our Food and Drug Administration be empowered by whatever means are necessary to inspect foreign candy plants that are sending tremendous quantities of confectionery into this country and make them adhere to the rigid standards that we are compelled to adhere to in this country. There is a lot to be desired in that area.

Mr. O'BRIEN. And the third point was the question of trinkets, and I assume that they are not nutritive. Would it be agreeable to your industry to have in the bill that we might report from this subcommittee a provision taking care of the trinket situation?

Mr. HEIDE. I believe our industry on the subject of trinkets would not actively oppose the change being recommended by Food and Drug. We do feel, however, that the present law adequately takes care of the situation and that there is no need to make any further revisions.

Mr. O'BRIEN. Do you feel that the practical effects of this discrimination, obvious discrimination against one industry, will become worse as time goes by?

In other words, there seems to be a tendency, on the part of the Government at least, to let sleeping dogs lie; why change the law.

If that persists for some time will that hurt the industry?

Mr. HEIDE. I believe it would have a cumulative effect as time goes on. While the substances that we are thinking about and have thought about for many years are relatively few in number, with the fantastic developments being made in the food industry, all segments of it, and in the field of food chemistry, there will be many substances available improving the quality of the food throughout the food industry that we would very much like to have the use of, if they are safe and are permissible to the other segments of the food industry.

Mr. O'BRIEN. Thank you very much, Mr. Chairman.

Mr. ROBERTS. The gentleman from Ohio.

Mr. SCHENCK. Thank you, Mr. Chairman. I heard part of Mr. Heide's statement and read the rest of it and I have also read the statement here by the Food and Drug Administration.

It would just appear to me that if an additive is safe, it is safe, period, and it ought to be permitted to be used in any manner in which it is safe to be used.

I just don't personally agree for the position that seems to have been arbitrarily taken by the Food and Drug Administration on this point. That is all, Mr. Chairman.

Mr. ROBERTS. Thank you. Mr. Rogers from Florida.

Mr. ROGERS of Florida. Thank you, Mr. Chairman.

Mr. Heide, I think your statement has pointed up the problem to the committee quite clearly. I share Mr. O'Brien's concern perhaps that we should put in something about trinkets just to be doubly safe, which I would think you would have no objections to.

I am concerned a little bit about the Department's comment about talc. Is talc used in candy to any great degree in this country?

Mr. HEIDE. To my knowledge, Mr. Rogers, it is not used to any great degree in this country.

Mr. ROGERS of Florida. What is talc? Is that the same thing they use as talcum powder?

Mr. HEIDE. I believe it is the same thing as the talc that is mined for making talcum powder. If I may say this, if talc is safe, why should there be any objection to it? I frankly believe that what is being said here by Food and Drug sort of conveys the impression that you could take a nice, good, wholesome American candy bar as it is made today or a piece of confectionery and do away with the butter, and the eggs, and the chocolate, and the nut meat, and all the things that are in it today and some day make a candy bar that

is composed of talc, and believe me, gentlemen, this wouldn't be on the candy stands for 30 days because nobody would eat it, and I think what we are talking about in the use of talc is, if it is a filler, it is part of the total mass, not the major portion.

Mr. ROGERS of Florida. Yes. I notice that in their letter that you have included in your statement they say on page 2:

We have also encountered consignments of candy made with talc and have uniformly proceeded against such lots under the authority of the present section 402(d).

Do you know whether talc is permitted to be used in other foods?

Mr. HEIDE. If it is safe under the law, yes.

Mr. ROGERS of Florida. That is right; it would seem to indicate that they have moved against any candy that included talc.

Mr. HEIDE. If talc is safe but nonnutritive they move against it under the law, 402(d).

Mr. ROGERS of Florida. But you feel that the food additive law would fully cover this situation because if it were not safe they could move against it?

Mr. HEIDE. Yes, sir.

Mr. ROGERS of Florida. But they couldn't move against it simply because it was not nutritive.

Mr. HEIDE. No, sir.

Mr. ROGERS of Florida. If we make the change.

Mr. HEIDE. If you make the change.

Mr. ROGERS of Florida. Does a nonnutritive substance mean it doesn't have very many calories?

Mr. HEIDE. I think under strict interpretation "nonnutritive" means it has no calories.

Mr. ROGERS of Florida. That might be added incentive for people to eat more candy, might it not? It might in my case.

Mr. HEIDE. I don't believe that the nonnutritive—

Mr. ROGERS of Florida. Constitutes that much.

Mr. HEIDE. Is that important?

Mr. ROGERS of Florida. I am very sympathetic to your problem, and I think the industry is being treated unfairly.

Mr. HEIDE. Thank you.

Mr. ROGERS of Florida. Thank you. Thank you, Mr. Chairman.

Mr. ROBERTS. I thank the gentleman. The gentleman from Minnesota?

Mr. NELSEN. One question only. Is it possible, if this relaxation in the procedure is permitted, that we would get a candy where, for example, volume has been achieved by some additive that may be nonnutritive, but simply to create volume and perhaps flavor to sell something of little value? Is that possible?

Mr. HEIDE. I just don't see it. I have been in the industry for 33 years and I have a broad knowledge of the industry in general. I am not a technical person. I have been aware of the nonnutritive problem as far as all of our industry is concerned, but, again, the consuming public is very discriminating. They have never had a finer variety of food products to choose from in all segments of the food industry, and all you have to do to be convinced of that is to go into your local supermarket, so the man who doesn't produce a good quality product, that is not delivering good value to the consumer, doesn't stay in the marketplace very long.

Mr. NELSEN. I wish to thank you for your statement and I would like to also say this: That it seems to me it is now an admitted fact by the Department that some change needs to be made, and I want to thank you for your fine statement which will be very helpful to the committee. Thank you.

Mr. HEIDE. Thank you, Mr. Nelsen.

Mr. SCHENCK. Will the gentleman yield?

Mr. NELSEN. Yes.

Mr. SCHENCK. A question was raised here which had something to do with the question of testing purely imported candies, setting up standards for imported candies. The Food and Drug Administration sets up standards for the efficacy and the purity and side effects and everything else of medical supplies that are made in various countries and shipped in here, so they certainly could set up the necessary rules and regulations, including the necessary manufacturing facilities, to cover any imported candy if it is necessary.

Mr. HEIDE. If I may just say one thing, Mr. Harvey commented on some weird, I think he referred to them as, confections coming into this country during World War II and I know that this is absolutely the truth. That is why I say the emphasis should be on the facilities where these products are produced rather than on quibbling about a few nonnutritive materials that would benefit our industry here in this country, but during World War II people were desperate to get candy wherever they could get it.

We were severely rationed as far as sugar was concerned. We were only able to deliver limited quantities, and such candy that came out disappeared from the counters very quickly, but we did get substantial quantities of candy from offshore, from the Caribbean area and places like that, and those factories down there where they were making what they call slab work, on a slab such as this table, where they would spread a nougat—a nougat has some honey in it and honey will attract the bee—when they had this out on the tables the insects were attracted by this smell of the honey in the confectionery and because they had windows in the factory but they had no screens and they had not glass in the windows, the bees came in and they sat on the candy and some of these bees were actually left in that candy when it was packaged and sent into this country.

I state again let's get to the source of the trouble and let's get to these factories wherever they may be and bring them up to our level. We have standards that are far ahead of many foreign manufacturers and we feel that this is the source of the foreign import problem.

Mr. SCHENCK. May I ask one other question there? How do you make so-called dietetic candy that must be pretty low in caloric content.

Mr. HEIDE. Dietetic candies are made from low caloric materials and they are identified as such, and I believe that under the law the product must be identified so that the purchaser knows that he is buying a dietetic confection and not a regular confection.

Mr. SCHENCK. Just one other observation. It would seem to me that I have heard somewhere that chocolate-covered grasshoppers are supposed to be very delicious, so I wouldn't think the bee in the nougat to which you referred would make much difference.

Mr. BROTZMAN. Will the gentleman yield for one question?

Mr. NELSEN. I guess I have the floor. I yield.

Mr. BROTZMAN. I want to be sure I understood one thing in Commissioner Harvey's statement. Would I understand that candy which came in from a foreign country would not have to be subjected to as rigid qualifications as would candy of a domestic manufacturer and producer of candy?

Mr. HEIDE. I cannot answer that question. I think the Department could answer that question for you, Mr. Brotzman. I don't know exactly what their standards and their tests are on imported confections. I am certain that if they contained any harmful ingredients or materials they certainly would move right in and do what had to be done, but apart from that I am not qualified to answer.

Mr. BROTZMAN. I realize it would better be directed to the Department. Of course that would seem patently unfair, but also unsafe, shall we say, if we imposed certain restrictions on domestic producers of confectionery but none on producers of confectionery that was coming in from abroad. It wouldn't make any sense to me. Well, you have the floor.

Mr. NELSEN. Yes. It would seem to me in a shipment of a foreign-made product the big problem is the availability of inspection of the plant, the facilities, and physical inspection, and the only way you can really determine it is by analysis, which is quite difficult and I suppose time consuming. Isn't that correct?

Mr. HEIDE. Yes. You could determine, Mr. Nelsen, the quality of the product by such examination, but you could not determine the conditions under which the product was made. I believe this gets into the area of the State Department and arrangements with other governments permitting such inspections, and I understand it is quite complicated.

Mr. NELSEN. Thank you very much.

Mr. ROBERTS. The gentleman from Texas?

Mr. PICKLE. I just wondered what kind of foreign candies are imported? You say some of them are imported in large quantities. What are some of them?

Mr. HEIDE. There is a tremendous amount of hard candy, taffies, the pulled candies, mostly wrapped candies. There are considerable quantities of chocolate products that come into the country and it is on an ever-increasing scale.

The ratio of imports versus our exports is about 6 to 1 on imports over our exports.

Mr. PICKLE. Where do they come from primarily; do you know.

Mr. HEIDE. They come from England; they come from Italy; they come from many countries. They come from the continent of Europe, Switzerland, and Holland also is quite a producer.

Mr. PICKLE. That is all, Mr. Chairman.

Mr. ROBERTS. The gentleman from Colorado?

Mr. BROTZMAN. Thank you, Mr. Chairman. I will say from what I have heard of your testimony and the other testimony here today I am receptive to your position. There may be a technical problem or two to work out the correct language and the correct bill. I wouldn't want to pass judgment on that point as yet.

I do understand that it is your position that the language suggested by Mr. Harvey on pages 4 and 5 of his testimony is not acceptable.

Mr. HEIDE. This added proviso that they wish to incorporate?

Mr. BROTZMAN. Yes. It starts "provided further."

Mr. HEIDE. Is not acceptable, no.

Mr. ROGERS of Florida. Would the gentleman yield?

Mr. BROTZMAN. Yes.

Mr. ROGERS of Florida. As I understand, you would have no objection to the additional amendment on page 5 which pertains to trinkets.

Mr. HEIDE. We would not actively oppose it, Mr. Rogers, but we feel it is already provided for under the law.

Mr. ROGERS of Florida. But you have no objection to this language as such, do you?

Mr. HEIDE. No strenuous objection; no, sir.

Mr. ROBERTS. Thank you. Anything further?

Mr. BROTZMAN. I have no further questions.

Mr. ROBERTS. This will conclude the hearing on H.R. 4731. I have a statement here I would also like to include, filed by the Corn Industries Research Foundation, Inc.

(The statement referred to follows:)

CORN INDUSTRIES RESEARCH FOUNDATION, INC.,
Washington, D.C., April 27, 1964.

Subject: H.R. 4731, a bill to amend section 402(d) of the Federal Food, Drug, and Cosmetic Act.

HON. KENNETH A. ROBERTS,
Chairman, Subcommittee on Public Health and Safety,
New House Office Building, Washington, D.C.

DEAR MR. ROBERTS: The Corn Industries Research Foundation, Inc., and its members have a direct interest in H.R. 4731 and support the proposed amendment to the extent that it would serve to eliminate the prohibition against the use of any nonnutritive article or substance as now provided in section 402(d) of the Federal Food, Drug, and Cosmetic Act.

The membership of the foundation consists of producers of corn starch, corn sirup, corn sugar, or other corn products manufactured by the wet milling process. Its present membership includes all but one of the producers engaged in this business in the United States.

While the direct interest of our industry is restricted as indicated, this restriction in our presentation should not be considered in any way as opposing the amendment as proposed. However, it is felt that our industry should, in all propriety, restrict its comments to the specific problem which it wished to have corrected by a suitable revision of section 402(d).

We respectfully propose that the words "nonnutritive article or substance" be deleted from section 402(d); or, if not deleted, then that the phrase be at least so qualified that nonnutritive substances required for technical reasons in the preparation of confections be permitted.

Our industry's specific interest in this suggestion lies in the use of mineral oil in a type of starch especially prepared for the confectionery industry commonly called molding starch, where it is necessary to add a small amount of mineral oil to the starch for the reason and in the manner hereinafter indicated, in order to render it suitable for its intended use.

Mineral oil is a nonnutritive substance. When following normal commercial practices in the use of molding starch, minute quantities of the mineral oil will adhere to the confection. The amount of mineral oil which remains in the finished confection is substantially less than the maximum of 0.6 percent specified as being suitable and safe for use in foods, as provided in Food Additive Regulation, section 121.1146, published in the Federal Register for March 12, 1964. However, it has been ruled administratively that the presence in confections of even these small amounts of mineral oil, introduced incidentally during the process of manufacture, constitutes a violation of the nonnutritive provisions of section 402(d).

Our suggested amendment of section 402(d) would make such use of mineral oil lawful.

The following is a more detailed outline of the use of molding starch and the need for the use of mineral oil in its preparation:

Mineral oil not in excess of 0.3 percent on a total weight basis is added to corn starch to impart the physical characteristics required of starch for making and holding impressions for molds of various designs utilized for molding confections, and particularly the various sizes and shapes of chocolate-covered candies. Corn starch so treated is commonly identified as "molding starch" in the trade. It is packaged or bagged by the respective manufacturers and, as so packaged or bagged, is shipped to the members of the confectionery industry.

As employed by the confectionery industry, the molding starch is placed on trays attached to endless conveyor belts in which it is spread out evenly in the powdered form so as to present a level surface. As these filled trays pass along the belt, molds necessary to effect the desired impressions are pressed into the starch, thus leaving an impression of the size and shape desired for the particular kind of candy to be molded. From there the trays pass on to the filling machines which deposit the molten candy mix into the impressions in the starch.

After the candy has had an opportunity to cool and harden, it is removed from the molding starch by brushing or by air blast, or by both, and the starch thus removed from the trays and the candy is dropped on a return conveyor which takes it back to the beginning of the production line for reuse as described. Additional quantities of molding starch are added to the production line from time to time in order to maintain a constant supply for use in molding candy. The supply of molding starch is constantly being conditioned by use of magnetic traps, sifters, driers, and coolers, or like equipment.

Mineral oil in the amount indicated, namely, 0.3 percent on a total weight basis in the starch, is added to the corn starch, solely for the purpose of imparting the necessary characteristics to the starch so that it will make and hold the desired impression and form so as to insure a firm mold and hence a regular outline and smooth surface for the confection deposited in the impression. It is not added for the purpose of imparting, nor does it impart, any characteristics whatsoever to the confection molded in the starch as described.

Thus, the only mineral oil which may become a component of the confection as the result of having been formed and shaped in the impressions in the molding starch is the infinitesimal quantity which may migrate incidentally from the starch which may continue to cling to the confection after cleaning. Good manufacturing practices require that as much of the molding starch be removed from the confection as is practicably possible. Studies have been conducted to determine the quantity of molding starch which continues to cling to the confection after the confection has been submitted to the cleaning processes followed in good manufacturing practices. Such a study with five different kinds of confections showed that the residue of mineral oil in the finished confection is about one-fourth of 1 percent of that specified as the maximum allowed for use in foods generally by the food additive regulation cited above.

We respectfully request, therefore, that section 402(d) of the Federal Food, Drug, and Cosmetic Act be amended as we have proposed for the reasons indicated.

Respectfully submitted.

WILLIAM J. HOOVER,
Administrative Vice President.

Mr. ROBERTS. This will conclude the hearings and the committee will stand in recess for consideration of certain matters in executive session.

Mr. HEIDE. Mr. Chairman, I would also like to take this opportunity to thank you for this opportunity of testifying here today. Thank you.

Mr. ROBERTS. Thank you for your appearance.

(Whereupon, at 11:37 a.m., the subcommittee adjourned.)



