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Manufacturing Chemists' Association, Inc.

(FOUNDED 1872)

1825 CONNECTICUT AVENUE, N. W.
WASHINGTON, D. C. 20009

August 11, 1967

TO: Members of the Food, Drug, and Cosmetic Chemicals Committee

SUBJECT: Food Additives Procedural Regulations

Gentlemen:

The attached notice of Proposed Rule Making may be of interest to you.

Sincerely yours,

Morgan M. Hoover

MMH:sjg

Attachment

Proposed Rule Making

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 121]

FOOD ADDITIVES

Procedural Regulations

The Commissioner of Food and Drugs proposes that the procedural food additive regulations be revised as set forth below to obtain improvement in the quality and organization of food additive petitions submitted and to expedite their scientific review by the Food and Drug Administration. The need for such revision is based on the following:

A. Almost half of the food additive petitions as originally submitted to the Food and Drug Administration have been incomplete or have not adequately supported the regulation requested and, therefore, have required subsequent supplementation, amendment, withdrawal, or denial.

B. Scientific review of deficient and poorly organized petitions is an unnecessary burden that wastes the time and efforts of both Administration and industry scientists.

Therefore, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (secs. 409, 701(a), 52 Stat. 1055, 72 Stat. 1786; 21 U.S.C. 348, 371(a)) and under the authority delegated to the Commissioner by the Secretary of Health, Education, and Welfare (21 CFR 2.120), it is proposed that Part 121 be amended by revising §§ 121.7, 121.9, and 121.51 and by adding § 121.50, as follows:

§ 121.7 *Food additives for use in feed and drinking water of animals and food additives that are also new drugs, certifiable antibiotic drugs, and/or pesticides.*

(a) (1) A substance that is a new drug within the meaning of section 201(p) of the act or an antibiotic drug subject to the certification requirements of sections 502(l) and 507 of the act may also be a food additive within the meaning of section 201(s) of the act because the substance is to be used in the feed of an animal or because its intended use in or on the animal results or may reasonably be expected to result directly or indirectly in it or its conversion product(s) becoming a component of or otherwise affecting the characteristics of a food derived from the animal.

(2) An application for a new drug or an antibiotic drug which substance is also a food additive shall be submitted in the form prescribed by § 130.4 of this chapter (Form FD 356V) and processed in accordance with Parts 130 (new drug) or 146 (antibiotic drug) of this chapter, and the food additive aspects of such applications shall be processed simultaneously.

(3) An application for a new drug or an antibiotic drug which substance is also a food additive shall include a practical, chemical assay method for enforcement of any tolerance provided and, if edible products of food-producing animals are involved, data establishing the residues of the substance or its metabolites in such edible products.

(b) Petitions for food additives that are nondrug substances for use in the drinking water or feed of animals shall be submitted in the form described in § 121.50 and shall be processed in accordance with the procedures prescribed in this Part 121.

(c) Any pesticide chemical added to processed feed for animals for the purpose of affecting such animals will be considered a food additive and new drug subject to approval under sections 409 and 505 of the act. Petitions for such pesticide chemicals shall be submitted and processed in accordance with paragraph (a)(2) of this section.

(d) A new-drug application will not be approved for a use that results in the substance becoming a food additive until a regulation therefor is established under section 409 of the act. A food additive regulation under section 409 of the act will not be established if the additive results from the use of a new drug for which a new-drug application cannot be approved. The new-drug application and the establishment of a regulation regarding the food additive aspects will be acted on simultaneously.

(e) Applications for use of any drug substance in feed or for a drug or antibiotic substance intended to be administered to a food-producing animal shall be submitted to the Bureau of Veterinary Medicine of the Food and Drug Administration for evaluation.

§ 121.9 Food additive master files.

(a) Any person submitting or intending to submit a food additive petition may submit confidential information or information entitled to protection as a trade secret in the form of a "food additive master file." Such master file will be assigned a number and will be retained as available material that may be incorporated in any food additive petition upon request from the person submitting such file.

(b) The material in the master file shall be arranged and indexed by page numbers as if it were a portion of a petition so that specific material may be precisely referenced in any separate subsequent petition.

(c) The analytical methods and a summary of the toxicological basis on which a food additive regulation is based are not considered confidential or entitled to protection as trade secrets.

§ 121.50 *Content and form of food additive petitions.*

(a) Petitions to be filed under the provisions of section 409(b) of the act shall be submitted in triplicate, in the form described in paragraphs (c) and (d) of this section. Any material submitted in a foreign language shall be accompanied by an accurate English translation. Any published information used in support of the petition shall be submitted in reprint form. The petition must be signed by the petitioner or by an authorized attorney, agent, or official. If the petitioner or such authorized representative does not reside or have a place of business within the United States, the petition must also furnish the name and post office address of and must be countersigned by an authorized attorney, agent, or official residing or maintaining a place of business within the United States. All original, unpublished scientific studies supplied in the petition shall include identification of the scientists who did the work and their pertinent qualifications. The omission of any material required by this section shall be noted and the reasons therefor stated.

(b) Information previously submitted by the petitioner to the Food and Drug Administration may be incorporated in subsequent submissions provided specific reference to such information is made by giving the type of submission and the volume, page, and date submitted, and provided that the submission is in a food additive master file kept current by the petitioner, or is in another form of submission not over 10 years old. Confidential material entitled to protection as a trade secret, such as method of manufacture or process information, in food additive petitions or food additive master files furnished by a person other than the petitioner may also be incorporated provided use of such information is authorized in a written statement signed by the person who submitted the information or his successor in interest.

(c) Petitions shall be assembled in the manner prescribed in paragraph (c) of this section and submitted in a form suitable for binding, with all text double spaced on 8 x 10½-inch pages with a left-hand margin of approximately 1½ inches and a right-hand margin of approximately 1 inch. The left-hand margin shall be punched for a standard two-hole fastener (2¾-inch span) vertically centered therein. Each section shall have a section divider with index tab thereon bearing the section heading. The pages in each section shall be identified with the letter designation for the section and consecutively numbered.

(d) Petitions shall be transmitted by a cover letter in triplicate in the following form:

Petitions Control Branch.
Food and Drug Administration.
Department of Health, Education, and Welfare.
Washington, D.C. 20204.

GENTLEMEN: The undersigned, ________ submits this petition pursuant to section 409(b)(1) of the Federal Food, Drug, and Cosmetic Act with respect to ________________
(Name of food additive and proposed use)

The petition is attached and is submitted in the form described in § 121.50 (21 CFR 121.50) of the food additive regulations.

Sincerely yours,

Petitioner

By ________________
(Indicate authority)

Date ________

Countersigned by ________________
(Indicate authority)

Post office address ________________

____

Date ________

(c) The food additive petition shall contain:

I. Introduction (on section tab).

A. A detailed table of contents listing all items contained in the petition and the page numbers where located.

B. A well-organized and coherent general summary of the data in the petition and the petitioner's conclusions presenting a sound basis for the regulation requested and including the following information with references to the pages on which the detailed data in the petition may be found.

1. *Identity and composition.* The name of the additive and the specifications proposed to assure that the substance is of appropriate grade for the intended use and that it is of reproducible composition.

2. *Use.* The purpose which the additive is to serve including an estimate of the maximum as well as the average quantity of the food additive to be expected in the total daily diet of the consumer and including the basis on which the estimate is made.

3. *Technical effect.* Highlights of the data that have been developed to establish that the additive accomplishes the intended technical effect and that the amount sought to be used is no higher than that reasonably necessary to accomplish such intended technical effect.

4. *Methods.* Highlights of the data that establish that the analytical methods provided are practicable regulatory ones adequate to enforce the limitations considered necessary on the use of the additive.

5. *Toxicology.* Highlights of the studies provided to establish the safety of the proposed uses of the additive with an explanation of how the petitioner concludes that the proposed uses are safe, including summaries of any unfavorable results as well as the favorable. The highlights shall include the no-effect levels found in the several species of test animals and the maximum safe level in the diet of the consumer. The margins of safety between the no-effect level in the most sensitive species of test animals and the average level as well as the maximum level likely to occur in the total diet of the consumer should be stated, taking into consideration previously approved food additive uses for the substance and any comparable substances. Also included shall be a summary of the published literature dealing with the safety of the compound. If safety depends upon virtual lack of migration, the rationale shall be explained briefly.

II. Body of the petition.

A. Identity (on section tab).

This section shall identify the additive and the general use or combination of uses for which it is intended (i.e., direct additive, indirect additive, pesticide for food additive application, or radiation) and shall provide the following information, as applicable:

1. *Direct additive—a. Nomenclature and formulas.* i. Common or usual name: Unless the name is being proposed as the common or usual name, cite references to compendia that recognize the name as common or usual.

ii. Chemical name in accordance with the nomenclature rules of the Chemical Abstracts Service.

iii. Trade name(s) and other names used for the compound, including those used during experimental testing.

iv. Empirical formula(s).

v. Structural formula(s), if known or proposed.

vi. Molecular weight.

b. *Description of the additive.* i. Complete quantitative composition.

ii. Physical state at room temperature.

iii. Organoleptic characteristics.

iv. Manufacturing process(es), including raw materials and their specifications and the analytical techniques used to check the specifications.

v. Food grade specifications for the additive, including identity, minimum content of the desired component(s), and limitations on reaction byproducts and other impurities including specifically total heavy metals, arsenic, and lead. Each specification and limitation shall be supported by a description of the analytical methods used including data establishing the accuracy and reliability of these methods. Data from a suitable number of representative production batches of the additive shall be included to establish the range of impurities and byproducts to be expected and to show that the proposed specifications can be met.

vi. Reproducibility of the additive, including the production controls and assays employed to assure that a reproducible product will be manufactured.

vii. Stability data and, if indicated thereby, any expiration date to be shown on the labeling to assure the identity, strength, quality, or purity of the additive.

2. *Indirect additive—a. Nomenclature and formulas.* Indirect additives include substances incidentally present in a final product because of addition for functional use elsewhere in the production operation and substances that may reasonably be expected to become a component of food because of their presence in food-contact surfaces. The following shall be provided for each substance or its reaction product(s) incidentally present in the food from production use and for each substance in the food-contact surface, including polymeric materials, whether present because of addition in the manufacturing or as a result of a chemical reaction during the manufacturing, unless adequate reasons for omission are advanced for particular components.

i. Common or usual name: Unless the name is being proposed as the common or usual name, cite references to compendia that recognize the name as common or usual.

ii. Chemical name(s) in accordance with the nomenclature rules of the Chemical Abstracts Service.

iii. Trade name(s) and other names used for the compound, including those used during experimental testing.

iv. Empirical formula(s).

v. Structural formula(s), if known or proposed.

vi. Molecular weight, including for polymeric substances the molecular weight distribution in the basic resin and the average molecular weights and the methods used in making these determinations.

b. *Description of the additive.* i. Composition of the food-contact surface of packaging material or food-processing equipment.

ii. Physical description of the food-contact surface, packaging, or equipment material.

iii. Manufacturing process, including for food-contact surfaces the raw materials and their specifications that encompass the basic resin polymers and the adjuvents (such as plasticizers, stabilizers, preservatives, fillers, colorants, catalysts, etc.), along with the analytical techniques used to check the specifications and including for other incidental additives where, how, and why the additive or its precursor has been incorporated into the process.

iv. Specifications for the additive(s) in food-contact surfaces, including their identities, the minimum content of the desired component(s), and limitations or impurities including total heavy metals, monomers, catalyst residues, etc. Each specification and limitation shall be supported by a description of the appropriate analytical methods used, including data establishing the accuracy and reliability of these methods. Data from a suitable number of representative production batches of the food-contact surfaces shall be included to establish the range of impurities and byproducts to be expected and to show that the proposed specifications can be met.

v. Reproducibility of the food-contact surfaces, including the production controls and tests employed to assure that a reproducible product will be manufactured.

3. *Radiation.* This may include radiation of any wavelength in the electromagnetic spectrum.

a. Radiation and radiation source(s) proposed.

i. If an isotope, its identity and the type of encapsulation used.

ii. If a machine source (including source tubes), its complete description.

b. Furnish engineering data providing complete information on the geometry of the radiating mechanism, including the speed of movement by the radiating head, the radioisotope, and the number of curies in the source used (if isotopes), the voltage and amperage used (if machine), and the total time of exposure. A statement of the radiation flux calculated therefrom shall be included.

c. Furnish data providing complete information on the means to be used to control the exposure.

i. In the case of machines, furnish data showing the sensitivity of the means of controlling the power sources and the way in which recorders are coupled to produce records of the operating voltages and amperages.

ii. In the case of isotopes and machines, describe the nature of dosimeter and the frequency of the dosimetry and furnish data showing the dosimetry and phantoms to be used, including those data that show that the dosimeter readings adequately reflect the dose absorbed by the food during exposure.

B. Use (on section tab).

This section shall include information on the amount of the food additive proposed for use and the purposes for which it is proposed together with all directions, recommendations, and suggestions regarding the proposed use. The petitioner shall furnish an estimate of the maximum as well as the average quantity of the food additive to be expected in the total daily diet of the consumer, supporting assumptions and calculations shall be included. The petitioner shall describe the conditions of use that he concludes are in accordance with good manufacturing practice in any instance

wherein he proposes no stricter limitation. If the usage level is alleged to be without specific limitation, the levels of use under good manufacturing practice shall be supplied.

1. *Direct additives.* In the case of the additives intended to produce an effect in the food, data obtained by adequate methodology shall be submitted showing the fate of the food additive in the food, whether the food additive remains unchanged in such food, or whether it is converted to another substance by reason of oxidation, degradation, or reaction with components of the food or otherwise, and the degree of any such conversion. This section shall include specimens of all labels and labeling proposed for the direct food additive.

2. *Indirect additives.* If transfer to food results or may be reasonably expected to result from the use of a food additive in processing, in packaging material, or in food-processing and handling equipment, the petitioner shall describe the conditions of use in detail with respect to the individual foods or classes of foods contacted. Information on the conditions of use shall include such things as the temperature and period of contact and the ratio of weight of food to contact surface area. The petitioner shall furnish an estimate of the maximum as well as the average quantity of the food additive and its conversion products to be expected in the total daily diet of the consumer. This estimate shall be based on experimental migration data using the food itself or on extraction data using solvents that simulate various types of food. These data shall reflect the most severe conditions as well as the more usual conditions of the proposed usage. The food or the extracts are to be analyzed by methods of adequate sensitivity and reliability for the food additive components of the food-contact surface. Details of the analytical procedure must be furnished including sufficient data to verify the claimed sensitivity and reliability of the methods.

3. *Radiation.* In the case of radiation, this section shall include information on the dose ranges to be used and the purpose for which the radiation is proposed together with all directions, recommendations, and suggestions regarding the proposed use, including information on the Atomic Energy Commission licenses under which any isotopes are used. This section should also include specimens of labeling to be used on the radiation sources and any labeling to be used on the treated food.

C. Technical effect (on section tab).

This section shall be divided into the following subsections:

1. A detailed table of contents for this section. This may be reproduced from the original complete table of contents if the latter is sufficiently detailed.

2. A summary (an explanation) of what the petitioner claims this section shows.

3. An analysis and interpretation of the data provided by the use of tables, charts, graphs, pictures, statistical evaluation, or by whatever means is appropriate, including references to the page numbers of the raw data analyzed and interpreted.

4. The raw data as follows:

a. *Direct additives.* The raw data developed to establish that the food additive will have the intended physical or other technical effect for which it is being added to the food and to establish that the amount requested is not higher than the amount reasonably required to accomplish the intended physical or other technical effect. These data shall include control data in sufficient detail to permit an accurate evaluation of the technical effect of graduated levels of the additive when tested experimentally.

b. *Indirect additives.* If the food additive is a component of a food-contact article (food-packaging material or food-processing and handling equipment), data shall be furnished showing the level of migration. If its migration to food is a function of the concentration of the component in such food-contact article, data shall also be furnished showing that the proposed usage level of the substance in the food-contact article is the level reasonably required to accomplish the intended effect in such article. If residues of a food additive are present in processed food because the additive has been used in the production or processing of food and the residues do not accomplish an intended effect in such processed food, data shall be furnished showing that the proposed tolerance level reflects a reduction of such residues to the extent possible in good manufacturing practice.

c. *Radiation.* In the case of radiation, experimental data shall be submitted showing that the radiation dose proposed accomplishes the intended technical effect and does not exceed the amount reasonably required to accomplish the intended effect.

i. Information shall be included showing that there is no induced radioactivity in the food or packaging material or in the extractants therefrom. This can include a theoretical discussion, but some actual experimental data should be provided to support the theory advanced in the case of packaging materials, and in all cases where radiant energies exceed 10 million electron volts. If different radiation fluxes are to be used, those materials subject to the highest flux and dose contemplated shall be selected for testing for induced radioactivity. A description of the methodology and the sensitivity of the methods used to establish the absence of induced radioactivity in the treated foods or packaging materials shall be furnished.

ii. Data shall be provided to establish the extent, if any, to which the nutritive composition of the irradiated food has been altered by exposure of the food to the highest dose and under the highest fluxes expected. If any such changes are considered insignificant, they should be so designated and the reasons detailed for their claimed insignificance. The methodology employed shall be fully described, including data establishing the sensitivity and reliability of the methods.

iii. Data shall be provided to establish that the irradiated food has not been significantly altered in organoleptic or other physical characteristics so as to render the material otherwise unfit for food. In the case of a food ordinarily stored for a period of time at particular temperatures, data shall be included reflecting the results when the irradiated food is appropriately stored and/or shipped.

iv. Whenever the effect produced is related to a given dose of radiation, the basis upon which that dose is measured shall be included. If no actual dosimetry can be described, a full explanation shall be included detailing the way in which the reported dose has been calculated.

D. Methods (on section tab).

This section shall be divided into the following subsections:

1. The petitioner's evaluation of the analytical method(s) with respect to reliability, accuracy, precision, and practicability as a regulatory method shall be furnished.

2. If usage of the food additive requires a tolerance for the food additive or for a conversion product in order to protect the public health, a practicable regulatory method shall be furnished to enforce the tolerance. A practicable regulatory method is one that will provide satisfactory results within a reasonable period of time considering the rate at which the material sampled may be consumed or otherwise disposed of. It must be satisfactory for application to the raw, processed, and/or finished food; i.e., give consistent results when used by properly equipped and trained laboratory personnel. The method must be capable of quantitatively determining the food additive or the conversion product in the presence of the normal components of the food in which it is to be used and in the presence of any other chemicals, including food additives, that can be reasonably expected to be present in such food. Validation data must be included, i.e., blanks (untreated food) and recoveries (food with additive at various levels, including level of usage). The analytical method shall be written up in stepwise fashion with any critical steps indicated and explained.

3. In the case of an additive that is to be limited only to good manufacturing practice, the petitioner shall provide data on an analytical method suitable for determining the amount that has been added to the food, or provide information purporting to show that the good manufacturing practice level is not likely to be exceeded.

4. In the case of food-contact surfaces, the petitioner shall provide the tests to be used in checking the specifications proposed for the purpose of limiting to safe amounts the migration to food of the components of the food-contact surface.

E. Safety (on section tab).

This section shall contain the following subsections:

1. A detailed table of contents for this section. This may be reproduced from the original complete table of contents if the latter is sufficiently detailed.

2. An explanation of what the petitioner claims this section shows, including:

a. The petitioner's appraisal of the safety data.

b. The no-effect levels found in the several species of test animals.

c. The petitioner's conclusion on the maximum safe level in the diet of the consumer, stating the margin of safety.

3. An analysis and interpretation of the provided data by the use of tables, charts, graphs, statistical review, or any appropriate means. This shall include summaries of both the favorable and unfavorable data, with references to the page numbers of the raw data analyzed and interpreted.

4. The raw data upon which the safety conclusions are based. This section may be regarded as incomplete unless it includes full reports of adequate tests reasonably applicable to establish whether or not the food additive is safe for its intended use. The reports ordinarily shall include detailed data derived from appropriate animal and other biological experiments in which the methods used and the results obtained are clearly set forth. The petition shall not omit without explanation any reports of investigations conducted including any that would bias an evaluation of the safety of the additive.

F. Tolerances-regulation (on section tab).

This section shall contain a proposed regulation in the format established by the Food and Drug Administration, including proposed tolerances, if tolerances are required to assure that the contemplated use of the additive is safe.

G. Amendment (on section tab).

Full information on each proposed change of existing regulations shall be submitted with the changes to be made indicated by bracketing proposed deletions and italicizing revised or added material. Italics may be indicated by underlining.

(f) Data in a petition regarding any method or process entitled to protection as a trade secret will be held confidential and will not be revealed unless it is necessary to do so in a regulation, or in an administrative hearing preliminary to any

judicial proceedings under the act. The scientific bases of safety on which any food additive regulation rests including food additive analytical methods and a summary of the toxicological data are not considered confidential.

§ 121.51 Processing of food additive petitions.

(a) Within 15 days after receipt of three copies of the petition by Petitions Control Branch of the Food and Drug Administration, the petitioner will be notified of the assigned petition number and of the fact that his petition has been filed for scientific review, or will be notified that his petition has not been filed and why. During this period of 15 days, the new petition will be reviewed only for determining that data are present and suitably arranged for an efficient scientific evaluation. Unless otherwise indicated in the filing letter, the date of this notification letter becomes the date of filing of the petition for the purposes of section 409(b)(5) of the act.

(1) If the petition cannot be filed, two of the three copies of it will be returned to the petitioner. One copy of the submitted material will be retained as an official record. The extra copies of the unfiled petition are returned so that if the petitioner supplements the original material, the supplemented petition can be submitted as a completely rearranged and indexed document in triplicate for reconsideration by the Food and Drug Administration.

(2) The petitioner may, after receiving a letter refusing the filing of his petition, return the two copies to the Petitions Control Branch and state in writing that he is resubmitting the petition to be filed over protest. In this case, it will be filed and the petitioner so notified. The fact that the petition has been filed over the Food and Drug Administration's protest will be included in the published notice of filing.

(b) A notice of filing will be published in the FEDERAL REGISTER within 30 days following the petition's filing date. The notice of filing shall contain the name and post office address of the petitioner, the name of the additive(s), and a description of the proposed use(s) in general terms or as appropriate. A copy of the notice will be mailed to the petitioner when the original is signed and forwarded for publicaton in the FEDERAL REGISTER. The publication of the notice of filing is to give notice to interested parties and is required by section 409(b)(5) of the act. The notice of filing is not to be construed as the promulgation of a regulation or amendment to a regulation.

(c) If upon a complete evaluation of the petition the Commissioner determines that additional information or an examination of samples or both are required to resolve questions regarding safety of the use of the additive, or the physical or other technical effect it produces, he may request such information or samples of the food additive, including the food-contact article containing the food additive, substances used as components of the food additive, and the food with which the food additive is used or contacts. The Commissioner will specify in the requests for samples a quantity deemed adequate for any study or investigation reasonably required with respect to the safety of the use of the food additive, or the physical or other technical effect it produces. The date used for computing the 90- or 180-day limit for the purpose of section 409(c)(2) of the act shall be moved forward one day for each day taken by the petitioner to submit the samples requested, beginning with the mailing date of the request. If the information or sample is requested a reasonable time in advance of the 180 days, but is not submitted within such 180 days after filing of the petition, the petition will be considered withdrawn without prejudice. A copy of the notice of withdrawal will be mailed to the petitioner when the original is signed and forwarded for publication in the FEDERAL REGISTER.

(d) If upon completion of the scientific reviews the petition and other relevant data have been found to support a regulation, the Commissioner will forward for publication in the FEDERAL REGISTER, within 90 days of the filing of the petition (or 180 days if the time was extended pursuant to sec. 409(c)(2) of the act), a regulation or amendment to a regulation prescribing the conditions under which the food additive may be safely used including, but not limited to, identification of the particular food or class(es) of food in which or in contact with which such additive may be used, the maximum quantity that may be used or permitted to remain in such food, the manner in which such additive may be added to or used in contact with such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use, and the Commissioner shall notify the petitioner of such order.

(e) If upon completion of the scientific reviews the petition and other relevant data have not been found to support a regulation, the petitioner will be so informed and given the reason therefor and will be offered an opportunity to withdraw the petition without prejudice to a future filing. If the petitioner does not withdraw the petition within 30 days of such notification, an order denying the regulation may be published in the FEDERAL REGISTER.

(f) If the Commissioner determines within 90 days of filing that additional time is needed to study and investigate the petition, he shall by written notice to the petitioner extend the original evaluation period for not more than 180 days after the filing of the petition.

Any interested person may, within 60 days from the date of publication of this notice in the FEDERAL REGISTER, file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 5440, 330 Independence Avenue SW., Washington, D.C. 20201, written comments, preferably in quintuplicate, on this proposal. Comments may be accompanied by a memorandum or brief in support thereof.

Dated: August 1, 1967.

JAMES L. GODDARD,
Commissioner of Food and Drugs.

[F.R. Doc. 67-9240; Filed, Aug. 7, 1967; 8:47 a.m.]