Second draft of collected comments with first proposed cover letter.

To DR. W. A. KNAPP
CONSULTANT – TOXICOLOGY
I.C. M-2

- ☐ FOR YOUR INFORMATION
- ☐ FOR YOUR FILES
- ☐ FOR YOUR COMMENTS
- ☐ PLEASE HANDLE
- ☐ PLEASE TAKE UP WITH ME
- ☐ FOR YOUR APPROVAL
- ☐ PLEASE REPLY WITH A COPY TO THIS OFFICE
- ☐ PLEASE PREPARE AN ANSWER FOR MY SIGNATURE
- ☐ PLEASE RETURN
- ☒ FOUND NOTHING OBJECTIONABLE EXCEPT THE DRAFTING OF THE PROPOSED REGS. THEMSELVES. THE BUSINESS ABOUT "IN REPRINT FORM" IS EVEN WORSE THAN THE ODD BALL PAPER SIZE (AMONG OTHER BOOBOOS)

FROM John H. Lehnert JL | DATE 2 Nov '67

C-323 (6-63) (F)

DRAFT

Hearing Clerk
Department of Health, Education and
Welfare
Room 540
330 Independence Avenue, S.W.
Washington, D. C. 20201

Dear Sir:

Pursuant to the proposed Procedural Regulations covering organization and handling of Food Additive petitions as published in the Federal Register of August 8, 1967, page 11443 et seq., we respectfully submit herewith comments of the Manufacturing Chemists' Association prepared with the assistance of its Food, Drug and Cosmetic Chemicals Committee.

Before proceeding with question and comment on wording and intent of the proposed regulation we would like to take this opportunity to express what we feel are basic difficulties in the administration of Section 409 of the Food, Drug and Cosmetic Act, particularly with relation to indirect additives.

Although the direct additives area of this section are probably of greatest concern to manufacturing chemists, we are also intimately concerned with components of packaging materials, both basic polymers and adjuvants, which may fall within the purview of the Act if meaningful migration occurs.

Much uncertainty arises in the determination of what constitutes meaningful migration. Administration policy notwithstanding, we maintain that the act of testing for migration is not in itself evidence that the additive may reasonably be expected to migrate. Modern analytical techniques will detect minute quantities of materials which may or may not be identifiable as coming from a packaging material but which may reasonably be expected to be toxicologically insignificant. We do not believe that it was the intent of Congress to control these very small amounts of relatively non-toxic migrants which usually can be detected from most packaging materials.

The plastic package of today and the adjuvants therein do produce migrants but at quite low levels and from which no deleterious effect has yet been demonstrated. We submit that the vast majority of adjuvants added in small quantity to packaging materials do not migrate in quantities which are toxicologically significant and should be exempt from exhaustive safety evaluation prior to marketing. In this connection, we refer you to the presentation of Dr. John P. Frawley before the September, 1966 meeting of the American

Chemical Society. In this he reaches the conclusion that " . . . any component of an article contacting food which is present in the article or its coating at a level not exceeding 0.2% by weight is generally recognized as safe provided it is not a heavy metal or pesticide." We submit that a practical solution might be to establish a realistic level for the components of a packaging material below which there need be no concern with migration, provided, of course, that the materials are known not to be highly toxic.

The purpose of this discussion is to urge that administrative policy be established and regulatory provision made for rapid acceptance of food additives which are present in packaging material in small quantity (e.g., <0.2%), or which would not be expected to be found in significant quantities (e.g., 0.1 ppm) in the daily diet.

The comments submitted herewith represent, in substance, comments submitted to the Manufacturing Chemists' Association by many of its member companies. It is expected that many of these companies will also submit their comments directly to the Food and Drug Administration. We respectfully urge the Commissioner to carefully evaluate our position on the proposed regulations and ask that appropriate changes be made in any final regulations that may issue. We strongly

urge that, in finalizing any regulations in this area and in evaluating the existing food additive regulations, especially those dealing with indirect food additives, that careful consideration be given to the substantive problems we have discussed regarding the administrative treatment and handling of these materials.

Second Draft of Collected Comments

§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.

§121.7 (a) (3)

We strongly urge that this Section be revised to delete the word "chemical." The limitation of acceptable assay methods to "chemical assays" is an unnecessary and illogical restriction as there may be practical biological, physical, or other methods which technically cannot be defined as chemical assays. To limit acceptable assay methods to chemical assays would unduly restrict the constant search by quality control personnel for better and more practical methods of assay, some of which may be better than chemical methods. We point out that neither Sections 505 nor 409 of the Federal Food, Drug, and Cosmetic Act require that assay methods relating to food additives be limited to chemical assay methods.

§121.9 Food additive master files.

§121.9 (a)

We request that the words "submitting or intending to submit a food additive petition" be deleted from the first sentence of this Section. In many instances, the person submitting a food additive master file is doing so for the benefit of another company or person; he, himself, may not intend to submit a food additive petition.

The last sentence of this same paragraph appears to limit the use of these master files to use in food additive petitions. Many materials are used as adjuncts in connection with foods, drugs, colors and pesticides.

In view of the voluminous nature of many of these master files, it is believed that one master file should suffice for all of these fields.

§121.9 (c)

We strongly urge that this subparagraph be deleted from the proposed regulation. Master files are submitted voluntarily and represent a confidential relationship between the Food and Drug Administration and industry. We believe that this relationship should remain, except wherein parts of the master file are incorporated in petitions by reference. For our comments on the confidentiality of analytical methods and toxicological data in a food additive petition, please refer to §121.50 (f).

§121.50 Content and form of food additive petitions.

§121.50 (a)

It is requested that the third sentence of this Section be amended to read as follows:

> Any published information used in support of the petition shall be submitted in reprint form, if available, or other suitable photocopy, and, in the event that the published material is readily available to FDA, references can be made to the publications in lieu of furnishing reprints or photocopies.

Under the existing regulation 121.51 "reprints or photostatic copies" of published information are permissible. We submit that the proposed regulations, restricting the petitioner to reprints is not practical and quite often will be impossible to meet. In some instances, reprints are not available for a number of reasons. We urge, therefore, that either reprints or

other suitable photocopies be allowed to support the food additive petition. In addition, where the published material is from a journal or other source readily available to FDA, the petitioner should be authorized to merely cite the journal or other source. This procedure is presently being used in the new drug and certifiable antibiotic areas (§130.37) and should also be adopted in connection with food additive petitions.

It is also requested that the sixth sentence which refers to unpublished scientific studies be amended to read as follows:

> All original unpublished scientific studies supplied in the petition shall include identification and a description of the qualifications including educational background and experience of the technical and professional personnel who are responsible for assuring the accuracy and reliability of such studies. This information need only be furnished for the person or persons who are the responsible head of the laboratory or scientific unit conducting the studies.

We point out that in many instances, it would be impractical to list the identity and qualifications of all the various chemists, toxicologists and other scientists or technical personnel who participated in the unpublished study presented in the petition. We point out that in regard to new drug applications §130.4 (c), subsection 2.8 (b) requires that the detailed educational and background information need only be given for the person responsible for assuring that the drug has the safety,

identity, strength, etc., which is claimed by the application. We submit that this information should only be required for the person responsible for the scientific studies presented in support of the food additive petition.

§121.50 (b)

Section 121.50 (b) provides for the incorporation by reference of previous submissions where the previous 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."

We do not understand the intent or meaning of this 10 year limitation. By implication, one could conclude that any data over 10 years old is deemed to be unreliable unless in a master file kept current. We suggest that many submissions whether part of master files (formerly designated "master files" or now designated "food additive master files"), petitions, new drug applications, or data leading to prior sanctions or approvals are of permanent value regardless of age. For example, detailed toxicological studies submitted in 1950 which led to a prior sanction or approval are still valid in many cases and data in food additive petitions filed since the effective date of the Food Additives Amendment may still be valid although over 10 years old.

The net effect of such a 10-year limit on submissions other than master file submissions is to force petitioners to establish master files for intentional or incidental food additive products. We see no justification for imposing this added burden on a petitioner whose formal petition filing should constitute an adequate file record.

The only burden petitioner should have in connection with the reference to data already on file with FDA is a requirement of an accurate description in sufficient detail to provide adequate identification thereof and a statement reaffirming the current validity of any conclusions therein.

For the above reasons, we would suggest deletion of the 10-year limitation for submissions other than those in a "master file kept current."

§121.50 (c)

This section prescribes paper size, line spacing, typing margins, hole punchings, etc., which must be used in connection with petitions. There are many reasons which would make compliance difficult. Some are the following:

(1) Except for legal purposes, the vast majority of U.S. business establishments use only 8-1/2" x 11" paper for correspondence, report writing, etc. It is difficult to obtain any other size from most stationers except on special order at extra cost. Carbon paper of different size presents similar difficulties.

(2) Photoreproduction papers are likewise of 8-1/2" x 11" dimension requiring hand trimming to bring to size prescribed.

(3) It is often desirable for the sake of completeness to include past studies rather than incorporate same by reference. The proposed regulation would require retyping of thousands of pages of text and photoreduction of graphs or pictures to bring to proper size.

(4) As noted in comments on §121.50 (a) above, reprints or photoreproductions of journal articles are usually not of the prescribed size and would require photoreduction or enlargement at needless and great expense.

(5) Similarly, reports of outside investigators (toxicologists, consultants, analysts, etc.,) are all on paper of 8-1/2" x 11" dimension and would require retyping or other reproduction to the size prescribed.

(6) File cabinets, file folders, record boxes, ring binders, etc., are made to accommodate 8-1/2 x 11" paper. While 8" x 10-1/2" paper can be used in these storage containers, 10% of storage spece therein is wasted.

(7) To the best of our knowledge, the vast majority of prior submissions have been on 8-1/2" x 11" paper. If §120.9 (b) means that master files must be converted to 8" x 10-1/2" paper "as if it were a portion of a petition" the task would be an impossible burden.

For the reasons stated above and probably additional complications not yet conceived, it is suggested that paper size requirement be deleted. Further, it is requested that double spacing be suggestive rather than obligatory or the requirement modified by "where practical." The retyping of large amounts of available material now in single space does not appear to be a reasonable requisite for food additive petitions.

§121.50 (e) I.B.2.

We request that this Section be amended to read as follows:

> USE. The purpose which the additive is to serve, including, if a direct additive, an estimate of the average quantity of the direct food additive to be expected in the total daily diet of the consumer, and where possible or practical, an estimate of the maximum quantity to be expected in the daily diet of the consumer. The bases for such estimates will be provided in this summary.

The introductory summary of use information required in this Part B for both direct and indirect additives is not practical as applied to indirect additives. Incidental or indirect food additives, whether food packaging or processing materials, do not lend themselves to meaningful estimates of either the average or the maximum levels that might be expected in the total daily diet. Food processing and packaging materials, unlike many direct food additives, generally can be used for across-the-board food contact use, thus coming into contact with countless types of foods under a variety of industrial processing and packaging use situations. Indeed, the petitioner for an indirect food additive in most cases will have no way of knowing all of the many packaging uses that the additive could be used for. We submit, therefore, that estimates of either the average or maximum quantities that might become part of the total daily diet will always be relatively meaningless figures; as such, this information should not be required for indirect additives.

We do not suggest the deletion of this requirement for indirect additives without pointing out that FDA has adopted and is presently following the philosophy that the 100-fold safety factor (100 times the no-effect level found in animals) adequately ensures the safety of indirect food additives and can logically be relied upon to take care of multiple variables such as diverse use and consumption. The text "Appraisal of the Safety of Chemicals in Foods, Drugs, and Cosmetics," published by the Association of Food and Drug Officials of the United States in 1959, was written by FDA staff members. This publication relates the sensitivity of man to various species of animals and reports that the highest ratio is that man is ten times as sensitive as the rat or cat. The safety factor of 100, then, provides another multiple ten-fold difference to protect man from possible adverse effects of a food additive.

The use of the factor of 100 was also endorsed by the Joint FAO/WHO Expert Committee on Food Additives. In the Second Report of this Committee, in the section entitled "Procedures for the Testing of Intentional Food Additives to Establish Their Safety for Use" (See WHO Technical Report Series No. 144, page 17,1958), the Committee concluded:

> "From these various investigations a dosage level can be established that causes no demonstrable effect in the animals used. In the extrapolation of this figure to man, some margin of safety is desirable to allow for any species difference in susceptibility, the numerical differences

> between the test animals and the human population exposed to the hazard, the greater variety of complicating disease processes in the human population, the difficulty of estimating the human intake and the possibility of synergistic action among food additives.
>
> "It will be useful to try to define here the standard daily dietary dose. This is taken to be the amount of the food additive that might be expected to be consumed by an average adult eating a normal diet as determined from some appropriate dietary survey. It should be assumed in these calculations that all the foods likely to be treated with the additive will contain it at the level proposed.
>
> "It is inescapable that some arbitrary factor must be applied in order to provide an adequate margin of safety. Where the maximum ineffective dose in animals is calculated in g/kg body-weight, a margin of safety of the order of 100 has been widely used. In the absence of any evidence to the contrary, the Committee believes that this margin of safety is adequate."

In addition to the deletion of the requirement of an estimated quantity of daily consumption of an indirect additive, we urge that as to <u>direct additives,</u> a petitioner need only estimate the average quantity of the direct food additive to be expected in the total daily diet of the consumer. It should be realized that an estimate of the average quantity will be a somewhat arbitrary figure, but an estimate of the maximum anticipated consumption will be even less meaningful. Again, we point out that the safety factor of 100 in judging the safety of the

particular direct food additive on the basis of animal toxicity studies was designed to take care of the variations in consumption by individual consumers.

§121.50 (e) I. B. 5.

For consistency with this entire Section 121.50, we request that the phrase "daily diet" be used wherever reference is made to the "diet of the consumer."

In addition, we request that the reference to "several species of test animals" in the second sentence be amended to read "in test animals." As a practical matter, normally only two species of test animals are required by FDA.

With respect to the third sentence of this Section, we strongly urge that it be amended to read:

> The margins of safety between the no-effect level in the most sensitive species of test animals and, with respect to direct food additives, the average level as well as the maximum level, where practical to determine, likely to occur in the total daily diet of the consumer should be stated, taking into consideration previously approved food additive uses for the substance and any toxicologically comparable substance. (Underlined language is new).

To support our request that the requirement for estimating average and maximum quantities of food additives to be consumed in a daily diet be limited to direct additives we refer to our comments on Section 121.50 (e) I. B. 2. In addition, we urge that the consideration given to "comparable substances" be limited to those substances that are known to be "toxicologically comparable."

It is well known that many substances are comparable from the standpoint of their effect or use in food but are not comparable from a safety or toxicity or chemical viewpoint.

§121.50 (e) II (A) (1) (b)

We find this subsection confusing in that several terms used therein appear to be descriptive of the same thing, namely, the chemical specifications for the food additive. Thus, "complete quantitative composition" (b.i.), "food grade specifications" (b.v.), and "reproducibility" (b.vi), all, we believe, mean substantially the same thing and would be best covered by the term "food additive specifications" or "food grade specifications." We submit that either of these terms adequately describes "complete quantitative composition" and "reproducibility" and request these items be deleted.

§121.50 (e) II. A. 1. b. iv.

It is requested that this subsection in describing food additives be amended to read:

> iv. Brief description of manufacturing process(es) and a listing of raw materials and their specifications.

We believe that a "brief description" of manufacturing process(es) should suffice for the purposes of evaluating the safety of the food additive petition by FDA. Detailed processing information would serve no real purpose. We would point out that once a petition is approved and a food additive regulation is published, any manufacturer may produce the additive using any manufacturing process

known, so long as the food additive meets the product specifications established in the applicable regulation and the manufacturer adheres to good manufacturing practice. The question arises as to whether petitioner would be bound to the process described in his petition. If so, the developer of the new facet of food technology would be placed at a severe disadvantage. We believe that the structure of §409 (b) of the Act, which details the requirements for a petition, supports the argument that production process information should be required only in special situations and not as a matter of routine.

In this regard, §409 (b) (2), subsections A through E thereof, lists the basic statutory requirements of data that must be included in a petition. No reference is made to production process information. A separate subsection of §409 (b), namely, (b) (3), deals with the problem of supplying, upon request of the Secretary, "a full description of the methods used in and the facilities and controls used for the production of such additive." Thus, we believe it was the intent of Congress to provide that the Secretary have the right to require such information where relevant because of special circumstances, but not merely as a matter of routine in every petition. Otherwise, a separate section (b) (3) would be meaningless since the requirement of production process information would have been listed in subsection (b)(2) of §409.

Finally, we also urge that the proposed requirement in this subsection for detailing the analytical techniques used to check the raw material specifications be deleted.

The important consideration is the final product specification and validation of the analytical methods used for the final product. In special situations, at the request of FDA, the description of specific analytical techniques could be provided to FDA but certainly they should not be required as a routine matter.

§121.50 (e) II. A. 1. b. v.

We request that the third sentence in this section be revised to delete the word "production" prior to the word "batches." Very often, at the time that the food additive petition is submitted no production batches have been prepared. Thus, it would be impossible for a petitioner to submit data from production batches. Data from either laboratory batches or controlled pilot plant batches should be sufficient to show the range of impurities and by-products to be expected and to show that the proposed specifications can be met.

§121.50 (e) II. A. 2. a. vi.

Deletion of this requirement is suggested. Methods presently available for determining molecular weight distribution of polymeric substances are generally complex and difficult to reproduce. We submit that extractive limitations for polymeric materials in selected solvents adequately reflect low molecular weight fractions which may be suspect toxicologically and that molecular weight distribution adds little to the appraisal of safety.

§121.50 (e) II. A. 2. b. iii.

Please refer to our comments on §120.50 (e) II. A. b. iv. with respect to requirements for manufacturing processes and analytical techniques used to check raw material specifications.

With respect to the specific wording of this paragraph, it is presumed that "adjuvants" referred to therein refers only to such adjuvants as are incorporated in the basic polymer polymerization and not to adjuvants in a resin formulation. To our knowledge, the final resin formulation has not been the subject of a petition nor is it intended that they should be. Such formulations are comprised of the basic resin to which may be added GRAS materials, adjuvants listed under the basic resin regulation and adjuvants otherwise permitted under Subpart F. as in regulations of the types represented by §121.2511, §121.2527 and §121.2541 as examples.

§121.50 (e) II. A. 2. b. iv.

As in §121.50 (e) II. A. 1. v. we submit that production batches are normally not available at the time of petitioning. Hence the word "production" should be deleted.

§121.50 (e) II. A. 2. b. v.

As in comment on §120.50 (e) II. A. 1. b. above, we submit that product specificationsas given in §121.50 (e) II. A. 2. b. iv. of the proposed regulation are the proper measure of reproducibility.

§121.50 (e) II. B.

For the reasons set forth in our comments under Section 121.50 (e) I. B. 2., we ask that the second sentence be amended to read:

> The petitioner shall furnish, if a direct additive, an estimate of the average quantity of the direct food additive to be expected in the total daily diet of the consumer, and where possible or practical, an estimate of the maximum quantity to be expected in the daily diet.

§121.50 (e) II. B. 1.

We strongly urge that the first sentence be amended so that the data required need only be given "if reasonably practical or possible to determine." This qualification should apply to all the data sought in this Section. We point out that the use information and specifications provided in the petition are designed to ensure the expected tolerable and safe level of the additive. The analytical methods are designed to measure the levels of the additive in a particular food or class of foods. The requirement in this proposed Section for showing the fate of the additive in food, conversion information, and possible reaction with other components of the food, is not necessary and very often, cannot be readily determined. As a practical matter, where final assays do not show an acceptable level of the direct additive, a petition is not likely to be approved by FDA.

§121.50 (e) II. B. 2.

Although migration data using actual and simulated foods will determine extent of transfer of a food additive in terms of milligrams per square inch of food contact surface under conditions of use, we submit that it will not provide information from which the average or maximum daily dietary intake can be calculated for reasons stated in §121.50 (e) I. B. 2. above. Accordingly, comments there are equally applicable to this subsection.

§121.50 (e) II. D. 2.

This subsection requires that in the case of the food additive needing a tolerance the regulatory method (analytical procedure) ". . . be satisfactory for application to the raw, processed, and/or finished food." This requirement is presumably intended for direct additives or those substances incidentally present in a final food product because of addition for functional use elsewhere in the production operation. We trust that this subsection is not intended to cover indirect additives as represented by extractives migrating from packaging materials. These extractives are multicomponent in character and in many cases it would be extremely difficult if not impossible to determine accurately amounts of individual components in food per se. Accordingly, it is suggested that this requirement be limited to direct additives and incidental additives (those substances incidentally present in a final food product because of addition for functional use elsewhere in the food production operation).

§121.50 (f)

For the reasons set forth below we request that this Section be amended to read:

> 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, and the petitioner approves of such regulation or in the alternative chooses to withdraw his petition, or in an administration hearing preliminary to any judicial proceedings under the Act. The analytical methods which do not reveal confidential processing information and the general summary of the toxicological basis on which a food additive regulation is based, as such general summary was presented and so designated in the petition, are not considered confidential or entitled to protection as trade secrets. Detailed descriptions of toxicological studies and the raw data of such studies will be considered confidential and entitled to protection from general disclosure. (Underlined language is new.)

It is our unified belief that (in process) analytical methods and toxicological data should be entitled to protection as are trade secrets and remain confidential The development of toxicological data and analytical methods are two of the most costly aspects of food additive petitions. While knowledge of (final product) analytical techniques may be necessary for enforcement purposes by FDA, and as such, ultimately disclosed in an enforcement action, no real need is seen for authorizing general public disclosure of such knowledge. Toxicological data, and even a summary thereof, is not necessary for enforcement purposes and should not under any circumstances be released as public information, unless the petitioner consents to such release

Arguments that disclosure of methodology and toxicological information are necessary to permit non-FDA experts to evaluate such methods and toxicological data are rebuttable as there are other means available to the FDA for substantiating this information as it appears in the food additive petition.

If it is deemed necessary to publish information concerning analytical methods in a regulation, the petitioner should be given the opportunity, prior to publication, to decide whether he wishes to have such information published or wishes to withdraw his petition.

We take particular note of the fact that Section 301 (j) of the Federal Food, Drug, and Cosmetic Act makes it an offense for any person to use to his own advantage or reveal to other than the secretary of officers or employees of the department or to courts under certain circumstances any information acquired under Sections 404, 409, 505, 506, 507, 704 or 706 concerning any method or process which as a trade secret is entitled to protection. We believe that the arbitrary designation of analytical methods and toxicology as non-confidential is in fact an attempt to usurp the function of the courts and goes beyond the authority granted to FDA by the legislature.

We must strongly request that Section 121.9 (c) be deleted, since the development of methodology may be a major expense involved in the development of a marketable food additive and in addition, we see no reason that the toxicological information in support of a food additive petition, also developed at a major expense to the petitioner, be released for public disclosure. If this request is not honored, we would ask that this Section be amended in accordance with the language set forth above.

§121.51 Processing of food additive petitions.

§121.51 (b)

It is suggested that this subsection be revised so as to delete the words "or as appropriate."

Section 409 (b) (5) of the Food, Drug and Cosmetic Act clearly states that "notice of the regulation proposed by the petitioner shall be published in general terms by the secretary within thirty days after filing." Congress has clearly not required the agency to specify in detail in a food additive proposal the specific claims made for the food additive. In the past, the agency has noticed human food additive proposals in the Federal Register on a broad general basis in accordance with the statutory authority. On the other hand, with respect to animal food additive petitions, the agency has set forth the proposal in great detail. It is suggested that human food additive proposals and animal food additive proposals should be treated equally, and both should be published in the Federal Register in general terms.

Publication of the details of a proposal (prior to approval) is an invitation for purchasers to use the food additive (particularly in animal feeds) for a use which has been proposed but not yet approved. The publishing of the proposal in general terms without reference to specific claims, would eliminate this possibility.

§121.51 (c)

If further information or sample is requested by FDA "a reasonable time in advance of 180 days, but is not submitted within such 180 days after filing the petition, the petition will be considered withdrawn without prejudice." It is suggested that "reasonable time in advance of 180 days" is too indefinite and that "180 days" implies that if added data are required the petitioner has no hope for a regulation within the 90 days provided by Section 409 (c) (2) of the Food, Drug and Cosmetic Act and little hope of obtaining a regulation within the statutory limit of 180 days. While we would hope that request for sample and/or additional data be made within 45 days after date of filing,a limit of 90 days would appear equitable. It must be recognized that the time required to provide information or sample may vary from days to months depending upon nature of the request. The petitioner should not be penalized by withdrawal of petition when, in fact, notice in advance of 180 days is not adequate to fill request.

§121.51 (d)

It is respectfully requested that petitioner be provided an opportunity to review language of a proposed regulation prior to publication in the Federal Register if it differs from that proposed by petitioner (§121.50(e)II.F.) and that this subsection be so revised.