§ 170.106 Notification for a food contact substance formulation (NFCSF).

(a) In order for the Food and Drug Administration (FDA) to accept an NFCSF, any food additive that is a component of the formulation must be authorized for its intended use in that NFCSF.

(b) FDA may publish a notice in the Federal Register stating that the agency has insufficient resources to review NFCSFs. From the date that this notice publishes in the Federal Register, FDA will no longer accept NFCSFs.

(c) An NFCSF must contain the following:

(1) A completed and signed FDA Form No. 3479; and

(2) Any additional documentation required to establish that each component of the formulation already may be marketed legally for its intended use.

21 CFR Ch. I (4–1–14 Edition)

PART 171—FOOD ADDITIVE PETITIONS

Subpart A—General Provisions

§ 171.1 Petitions.

(a) Petitions to be filed with the Commissioner under the provisions of section 409(b) of the Federal Food, Drug, and Cosmetic Act (the act) shall be submitted in triplicate (quadruplicate, if intended uses include use in meat, meat food product, or poultry product). If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The petition shall state petitioner’s post office address to which published notices or orders issued or objections filed pursuant to section 409 of the Act may be sent.

(b) Pertinent information may be incorporated in, and will be considered as part of, a petition on the basis of specific reference to such information submitted to and retained in the files of the Food and Drug Administration. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized in a written statement signed by the person who submitted it. Any reference to published information offered in support of a food
additive petition should be accompanied by reprints or photostatic copies of such references.

(c) Petitions shall include the following data and be submitted in the following form:

Name of petitioner
Post-office address
Date
Name of food additive and proposed use

Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740.

DEAR SIRS:

The undersigned, submits this petition pursuant to section 409(b)(1) of the Federal Food, Drug, and Cosmetic Act with respect to:

(Name of the food additive and proposed use)

Attached hereto, in triplicate (quadruplicate, if intended uses include use in meat, meat food product, or poultry product), and constituting a part of this petition are the following:

A. The name and all pertinent information concerning the food additive, including chemical identity and composition of the food additive, its physical, chemical, and biological properties, and specifications prescribing the minimum content of the desired component(s) and identifying and limiting the reaction byproducts and other impurities. Where such information is not available, a statement as to the reasons why it is not should be submitted.

When the chemical identity and composition of the food additive is not known, the petition shall contain information in sufficient detail to permit evaluation regarding the method of manufacture and the analytical controls used during the various stages of manufacturing, processing, or packing of the food additive which are relied upon to establish that it is a substance of reproducible composition. Alternative methods and controls and variations in methods and controls within reasonable limits that do not affect the characteristics of the substance or the reliability of the controls may be specified.

If the food additive is a mixture of chemicals, the petition shall supply a list of all substances used in the synthesis, extraction, or other method of preparation, regardless of whether they undergo chemical change in the process. Each substance should be identified by its common English name and complete chemical name, using structural formulas when necessary for specific identification. If any proprietary preparation is used as a component, the proprietary name should be followed by a complete quantitative statement of composition. Reasonable alternatives for any listed substance may be specified.

If the petitioner does not himself perform all the manufacturing, processing, and packaging operations for a food additive, the petition shall identify each person who will perform a part of such operations and designate the part.

The petition shall include stability data, and, if the data indicate that it is needed to insure the identity, strength, quality, or purity of the additive, the expiration date that will be employed.

B. 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, as well as specimens of the labeling proposed for the food additive and any labeling that will be required by applicable provisions of the Federal Food, Drug, and Cosmetic Act on the finished food by reason of the use of the food additive. If the additive results or may reasonably be expected to result from the use of packaging material, the petitioner shall show how this may occur and what residues may reasonably be anticipated.

(C) Petitions shall include the following data and be submitted in the following form:

Typewritten or other draft-labeling copy will be accepted for consideration of the petition, provided a statement is made that final printed labeling identical in content to the draft copy will be submitted as soon as available and prior to the marketing of the food additive.

(If the food additive is one for which a tolerance limitation is required to assure its safety, the level of use proposed should be no higher than the amount reasonably required to accomplish the intended physical or other technical effect, even though the safety data may support a higher tolerance.)

C. Data establishing that the food additive will have the intended physical or other technical effect or that it may reasonably be expected to become a component, or to affect the characteristics, directly or indirectly, of food and the amount necessary to accomplish this. These data should include information in sufficient detail to permit evaluation with control data.

D. A description of practicable methods to determine the amount of the food additive in the raw, processed, and/or finished food and of any substance formed in or on such food because of its use. The test proposed shall be one that can be used for food-control purposes and that can be applied with consistent results by any properly equipped and trained laboratory personnel.

E. Full reports of investigations made with respect to the safety of the food additive.

A petition may be regarded as incomplete unless it includes full reports of adequate tests reasonably applicable to show whether
§ 171.1

or not the food additive will be safe for its intended use. The reports ordinarily should 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 that would bias an evaluation of the safety of the food additive.

F. Proposed tolerances for the food additive, if tolerances are required in order to insure its safety. A petitioner may include a proposed regulation.

G. If submitting petition to modify an existing regulation issued pursuant to section 409(c)(1)(A) of the Act, full information on each proposed change that is to be made in the original regulation must be submitted. The petition may omit statements made in the original petition concerning which no change is proposed. A supplemental petition must be submitted for any change beyond the variations provided for in the original petition and the regulation issued on the basis of the original petition.

H. The petitioner is required to submit either a claim for categorical exclusion under § 25.30 or 25.32 of this chapter or an environmental assessment under § 25.40 of this chapter.

Yours very truly,

Petitioner

(Indicate authority)

(d) The petitioner will be notified of the date on which his petition is filed; and an incomplete petition, or one that has not been submitted in triplicate, will usually be retained but not filed as a petition under section 409 of the Act. The petitioner will be notified in what respects his petition is incomplete.

(e) The petition must be signed by the petitioner or by his attorney or agent, or (if a corporation) by an authorized official.

(f) The data specified under the several lettered headings should be submitted on separate sheets or sets of sheets, suitably identified. If such data have already been submitted with an earlier application, the present petition may incorporate it by specific reference to the earlier. If part of the data have been submitted by the manufacturer of the food additive as a master file, the petitioner may refer to the master file if and to the extent he obtains the manufacturer’s written permission to do so. The manufacturer may authorize specific reference to the data without disclosure to the petitioner. Nothing herein shall prevent reference to published data.

(g) A petition shall be retained but shall not be filed if any of the data prescribed by section 409(b) of the Act are lacking or are not set forth so as to be readily understood.

(h)(1) The following data and information in a food additive petition are available for public disclosure, unless extraordinary circumstances are shown, after the notice of filing of the petition is published in the FEDERAL REGISTER or, if the petition is not promptly filed because of deficiencies in it, after the petitioner is informed that it will not be filed because of the deficiencies involved:

(i) All safety and functionality data and information submitted with or incorporated by reference in the petition.

(ii) A protocol for a test or study, unless it is shown to fall within the exemption established for trade secrets and confidential commercial information in § 20.61 of this chapter.

(iii) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information, after deletion of:

(ia) Names and any information that would identify the person using the product.

(ib) Names and any information that would identify any third party involved with the report, such as a physician or hospital or other institution.

(iv) A list of all ingredients contained in a food additive, whether or not it is in descending order of predominance. A particular ingredient or group of ingredients shall be deleted from any such list prior to public disclosure if it is shown to fall within the exemption established in § 20.61 of this chapter, and a notation shall be made that any such ingredient list is incomplete.

(vi) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and is shown to fall within the exemption established in § 20.61 of this chapter.

(2) The following data and information in a food additive petition are not available for public disclosure unless they have been previously disclosed to the public as defined in § 20.61 of this chapter or they relate to a product or ingredient that has been abandoned.
and they no longer represent a trade secret or confidential commercial or financial information as defined in §20.61 of this chapter:

(i) Manufacturing methods or processes, including quality control procedures.

(ii) Production, sales, distribution, and similar data and information, except that any compilation of such data and information aggregated and prepared in a way that does not reveal data or information which is not available for public disclosure under this provision is available for public disclosure.

(iii) Quantitative or semiquantitative formulas.

(3) All correspondence and written summaries of oral discussions relating to a food additive petition are available for public disclosure in accordance with the provisions of part 20 of this chapter when the food additive regulation is published in the Federal Register.

(4) For purposes of this regulation, safety and functionality data include all studies and tests of a food additive on animals and humans and all studies and tests on a food additive for identity, stability, purity, potency, performance, and usefulness.

(i)(1)(i) Within 15 days after receipt, the Food and Drug Administration will notify the petitioner of the acceptance or nonacceptance of a petition, and if not accepted, the reasons therefor. If accepted, the petitioner will be sent a letter stating this and the date of the letter shall become the date of filing for the purposes of section 409(b)(5) of the act. In cases in which the Food and Drug Administration agrees that a premarket notification for a food contact substance (Food Contact Notification (FCN)) submitted under section 409(h) of the act may be converted to a petition, the withdrawal date for the FCN will be deemed the date of receipt for the petition.

(ii) If the petitioner desires, he may supplement a deficient petition after being notified regarding deficiencies. If the supplementary material or explanation of the petition is deemed acceptable, the petitioner shall be notified. The date of such notification becomes the date of filing. If the petitioner does not wish to supplement or explain the petition and requests in writing that it be filed as submitted, the petition shall be filed and the petitioner so notified.

(iii) Notwithstanding paragraph (i)(1)(ii) of this section, the petition shall not be filed if the Food and Drug Administration determines that the use identified in the petition should be the subject of an FCN under section 409(h) of the act rather than a petition.

(2) The Commissioner will publish in the Federal Register within 30 days from the date of filing of such petition, a notice of the filing, the name of the petitioner, and a brief description of the proposal in general terms. In the case of a food additive which becomes a component of food by migration from packaging material, the notice shall include the name of the migratory substance, and where it is different from that of one of the original components, the name of the parent component, the maximum quantity of the migratory substance that is proposed for use in food, and the physical or other technical effect which the migratory substance or its parent component is intended to have in the packaging material. A copy of the notice will be mailed to the petitioner when the original is forwarded to the Federal Register for publication.

(j) The Commissioner may request a full description of the methods used in, and the facilities and controls used for, the production of the food additive, or a sample of the food additive, articles used as components thereof, or of the food in which the additive is intended to have in the packaging material. A copy of the notice will be mailed to the petitioner when the original is forwarded to the Federal Register for publication.
Act shall be moved forward 1 day for each day after the mailing date of the request taken by the petitioner to submit the sample. 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.

(k) If nonclinical laboratory studies are involved, petitions filed with the Commissioner under section 409(b) of the Act shall include, with respect to each nonclinical study contained in the petition, either a statement that the study has been, or will be, conducted in compliance with the good laboratory practice regulations as set forth in part 58 of this chapter, or, if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(l) [Reserved]

(m) If clinical investigations involving human subjects are involved, petitions filed with the Commissioner under section 409(b) of the Act shall include statements regarding each such clinical investigation relied upon in the petition that it either was conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(2) FDA will ask USDA to advise whether the proposed meat and poultry uses comply with the FMIA and PPIA, or if not, whether use of the substance would be permitted in products under USDA jurisdiction under specified conditions or restrictions.

§ 171.7 Withdrawal of petition without prejudice.

(a) In some cases the Commissioner will notify the petitioner that the petition, while technically complete, is inadequate to justify the establishment of a regulation or the regulation requested by petitioner. This may be due to the fact that the data are not sufficiently clear or complete. In such cases, the petitioner may withdraw the petition pending its clarification or the obtaining of additional data. This withdrawal will be without prejudice to a future filing. Upon refiling, the time limitation will begin to run anew from the date of refiling.

(b) At any time before the order provided for in §171.100(a) has been forwarded to the Federal Register for publication, the petitioner may withdraw the petition without prejudice to a future filing. Upon refiling, the time limitation will begin to run anew.
§ 171.130 Procedure for amending and repealing tolerances or exemptions from tolerances.

(a) The Commissioner, on his own initiative or on the petition of any interested person, pursuant to part 10 of this chapter, may propose the issuance of a regulation amending or repealing a regulation pertaining to a food additive or granting or repealing an exception for such additive.

(b) Any such petition shall include an assertion of facts, supported by data, showing that new information exists with respect to the food additive or that new uses have been developed or old uses abandoned, that new data are available as to toxicity of the chemical, or that experience with the existing regulation or exemption may justify its amendment or repeal. New data

(c) Any petitioner who has a food additive petition pending before the agency and who subsequently submits a premarket notification for a food contact substance (FCN) for a use or uses described in such petition shall be deemed to have withdrawn the petition for such use or uses without prejudice to a future filing on the date the FCN is received by the Food and Drug Administration.


§ 171.102 Effective date of regulation.

A regulation published in accordance with § 171.100(a) shall become effective upon publication in the Federal Register.

§ 171.110 Procedure for objections and hearings.

Objections and hearings relating to food additive regulations under section 409(c), (d), or (h) of the Act shall be governed by part 12 of this chapter.

shall be furnished in the form specified in §§171.1 and 171.100 for submitting petitions.


PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

Subpart A—General Provisions

Sec.
172.5 General provisions for direct food additives.

Subpart B—Food Preservatives

172.105 Anoxomer.
172.110 BHA.
172.115 BHT.
172.120 Calcium disodium EDTA.
172.125 Dehydroacetic acid.
172.130 Dimethyl dicyanate.
172.135 Disodium EDTA.
172.140 Ethoxyquin.
172.145 Heptylparaben.
172.150 4-Hydroxymethyl-2,6-di-tert-butyl-phenol.
172.155 Natamycin (pimaricin).
172.160 Potassium nitrate.
172.165 Quaternary ammonium chloride combination.
172.167 Silver nitrate and hydrogen peroxide solution.
172.170 Sodium nitrate.
172.175 Sodium nitrite.
172.177 Sodium nitrite used in processing smoked chub.
172.180 Stannous chloride.
172.185 TBHQ.
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Subpart C—Coatings, Films and Related Substances

172.210 Coatings on fresh citrus fruit.
172.215 Coumarone-indene resin.
172.225 Methyl and ethyl esters of fatty acids produced from edible fats and oils.
172.230 Microcapsules for flavoring substances.
172.235 Morpholine.
172.250 Petroleum naphtha.
172.255 Polycryliclamide.
172.260 Oxidized polyethylene.
172.270 Sulfated butyl oleate.
172.275 Synthetic paraffin and succinic derivatives.
172.280 Terpene resin.

Subpart D—Special Dietary and Nutritional Additives

172.310 Aluminum nicotinate.
172.315 Nicotinamide-ascorbic acid complex.
172.320 Amino acids.
172.325 Bakers yeast protein.
172.330 Calcium pantothenate, calcium chloride double salt.
172.335 D-Pantothenamide.
172.340 Fish protein isolate.
172.345 Folic acid (folacin).
172.350 Fumaric acid and salts of fumaric acid.
172.355 Kelp.
172.370 Iron-choline citrate complex.
172.372 N-Acetyl-L-methionine.
172.375 Potassium iodide.
172.379 Vitamin D.
172.380 Vitamin D, vitamin D2, and vitamin D3.
172.381 Vitamin D, and vitamin D2.
172.382 Whole fish protein concentrate.
172.395 Xylitol.
172.399 Zinc methionine sulfate.

Subpart E—Anticaking Agents

172.410 Calcium silicate.
172.430 Iron ammonium citrate.
172.480 Silicon dioxide.
172.490 Yellow prussiate of soda.

Subpart F—Flavoring Agents and Related Substances

172.510 Natural flavoring substances and natural substances used in conjunction with flavors.
172.515 Synthetic flavoring substances and adjuvants.
172.520 Cocoa with dioctyl sodium sulfosuccinate for manufacturing.
172.530 Disodium guanylate.
172.535 Disodium inosinate.
172.540 DL-Alanine.
172.560 Modified hop extract.
172.575 Quinine.
172.580 Safrrole-free extract of sassafras.
172.585 Sugar beet extract flavor base.
172.590 Yeast-malt sprout extract.

Subpart G—Gums, Chewing Gum Bases and Related Substances

172.610 Arabinogalactan.
172.615 Chewing gum base.
172.620 Carrageenan.
172.622 Carrageenan with polysorbate 80.
172.626 Salts of carrageenan.
172.655 Furcellaran.
172.660 Salts of furcellaran.
172.665 Gellan gum.
172.695 Xanthan gum.

Subpart H—Other Specific Usage Additives

172.710 Adjuvants for pesticide use dilutions.