FDA Files Petition to Remove Clearance for Styrene and Other Synthetic Flavoring Substances

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January 14, 2016

The Food and Drug Administration (FDA) filed a food additive petition proposing that the food additive regulations be amended to no longer authorize the use of styrene and six other listed synthetic flavoring food additives, and to establish zero tolerances for the additives. The petition was submitted by the Center for Science in the Public Interest, the Natural Resources Defense Council, the Center for Food Safety, the Consumers Union, Improving Kids' Environment, the Center for Environmental Health, the Environmental Working Group, the Environmental Defense Fund, and James Huff.

Specifically, the petition proposes to amend Title 21 of the Code of Federal Regulations (C.F.R.) § 172.515, *Synthetic flavoring substances and adjuvants,* to no longer provide for the use of the following synthetic flavoring food additives and to establish zero tolerances for them:

- Benzophenone
- Ethyl acrylate
- Eugenyl methyl ether
- Myrcene
- Pulegone
- Pyridine
- Styrene

The petitioners contend that these substances are carcinogenic based on new data, including conclusions by the National Toxicology Program, the International Agency for Research on Cancer, and the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment. While the petition proposes to amend only § 172.515, FDA explained that its response to the petition could affect other regulations and clearances impacting these additives. For example, benzophenone is also approved for use as an indirect food additive, and ethyl acrylate, pyridine, and styrene are permitted for use by other food additive regulations and food contact notifications as reactants or manufacturing aids. However, the Agency noted that such uses are not the subject of these food additive regulations and food contact notifications, and as such, may not necessarily be affected if this petition results in a regulation.

FDA also pointed out that there is no statutory or regulatory provision for establishing a zero tolerance standard for flavoring food additives in § 172.515. However, Title 21 C.F.R. Part 189 permits FDA to prohibit the use of substances in human foods based on a determination that they present a potential risk to the public health or have not been shown by adequate scientific data to be safe for use in human foods.

- Would more, but shorter, sections be better?
- Are the requirements in the rules clearly stated?
- Have we organized the material to suit your needs?
- Could we improve clarity by adding tables, lists, or diagrams?
- What else could we do to make the rules easier to understand?
- Do the rules contain technical language or jargon that is not clear?
- Would a different format make the rules easier to understand, *e.g.* grouping and order of sections, use of headings, paragraphing?

Regulatory Procedures

Executive Order 12866 as supplemented by Executive Order 13563

We consulted with the Office of Management and Budget (OMB) and determined that these proposed rules do not meet the criteria for a significant regulatory action under Executive Order 12866, as supplemented by Executive Order 13563. Therefore, OMB did not review them.

Regulatory Flexibility Act

We certify that these proposed rules will not have a significant economic impact on a substantial number of small entities because it affects individuals only. Therefore, the Regulatory Flexibility Act, as amended, does not require us to prepare a regulatory flexibility analysis.

Paperwork Reduction Act

These rules do not create any new or affect any existing collections and, therefore, do not require Office of Management and Budget approval under the Paperwork Reduction Act.

(Catalog of Federal Domestic Assistance Program No. 96.006, Supplemental Security Income.)

List of Subjects in 20 CFR Part 404

Administrative practice and procedure; Blind; Disability benefits; Government employees; Old-age, Survivors and Disability Insurance; Reporting and recordkeeping requirements; Social security.

Dated: December 23, 2015.

Carolyn W. Colvin,

Acting Commissioner of Social Security.

For the reasons stated in the preamble, we propose to amend subpart E of Part 404 of title 20 of the Code of Federal Regulations as set forth below:

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950–).

Subpart E—[Amended]

■ 1. The authority citation for subpart E of part 404 continues to read as follows:

Authority: Secs. 202, 203, 204(a) and (e), 205(a) and (c), 216(l), 222(c), 223(e), 224, 225, 702(a)(5), and 1129A of the Social Security Act (42 U.S.C. 402, 403, 404(a) and (e), 405(a) and (c), 416(l), 422(c), 423(e), 424a, 425, 902(a)(5), and 1320a–8a); 48 U.S.C. 1801.

■ 2. In § 404.401, revise paragraph (a)(4) to read as follows:

§ 404.401 Deduction, reduction, and nonpayment of monthly benefits or lump-sum death payments.

* * * * *

(a) * * *

(4) An individual under full retirement age (see § 404.409) is concurrently entitled to disability insurance benefits and to certain public disability benefits (see § 404.408);

* * * * *

■ 3. In § 404.408, revise paragraph (a)(2)(ii) to read as follows:

§ 404.408 Reduction of benefits based on disability on account of receipt of certain other disability benefits provided under Federal, State, or local laws or plans.

* * * * *

(a) * * *

(2) * * *

(ii) The individual has not attained full retirement age as defined in 20 CFR 404.409.

* * * * *

[FR Doc. 2015–33036 Filed 12–31–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. FDA–2015–F–4317]

Center for Science in the Public Interest, Natural Resources Defense Council, Center for Food Safety, Consumers Union, Improving Kids' Environment, Center for Environmental Health, Environmental Working Group, Environmental Defense Fund, and James Huff; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by the Center for Science in the Public Interest, Natural Resources Defense Council, Center for Food Safety, Consumers Union, Improving Kids' Environment, Center for Environmental Health, Environmental Working Group, Environmental Defense Fund, and James Huff, proposing that the food additive regulations be amended to no longer authorize the use of seven listed synthetic flavoring food additives and to establish zero tolerances for the additives.

DATES: The food additive petition was filed on August 17, 2015. Submit either electronic or written comments by March 4, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential,

if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2015–F–4317 for "Center for Science in the Public Interest, Natural Resources Defense Council, Center for Food Safety, Consumers Union, Improving Kids' Environment, Center for Environmental Health, Environmental Working Group, Environmental Defense Fund, and James Huff; Filing of Food Additive Petition."

Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov*. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at *http://www.fda.gov/regulatoryinformation/dockets/default.htm*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Judith Kidwell, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 240–402–1071.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 409(b)(5) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348(b)(5)), we are giving notice that we have filed a food additive petition (FAP 5A4810) submitted by the Center for Science in the Public Interest, Natural Resources Defense Council, Center for Food Safety, Consumers Union, Improving Kids' Environment, Center for Environmental Health, Environmental Working Group, Environmental Defense Fund, and James Huff, c/o Thomas Neltner, 1875 Connecticut Ave. NW., Suite 600, Washington, DC 20009. The petition proposes to amend § 172.515 (21 CFR 172.515), *Synthetic flavoring substances and adjuvants*, to no longer provide for the use of seven listed synthetic flavoring food additives and to establish zero tolerances for these additives.

The seven food additives that are the subject of this petition are as follows:

- Benzophenone (also known as diphenyl ketone) (CAS No. 119–61–9);
- Ethyl acrylate (CAS No. 140–88–5);
- Eugenyl methyl ether (also known as 4-allylveratrole or methyl eugenol) (CAS No. 93–15–2);
- Myrcene (also known as 7-methyl-3-methylene-1,6-octadiene) (CAS No. 123–35–3);
- Pulegone (also known as *p*-menth-4(8)-en-3-one) (CAS No. 89–82–7);
- Pyridine (CAS No. 110–86–1); and
- Styrene (CAS No. 100–42–5).

II. Amendment of § 172.515

In accordance with the procedures for amending or revoking a food additive regulation in § 171.130 (21 CFR 171.130), the petition asks us to amend § 172.515 to no longer provide for the use of these seven food additives as synthetic flavoring substances. Specifically, the petitioners contend that new data establish that these substances are carcinogenic and are, therefore, not safe for use in food under the Delaney Clause (section 409(c)(3)(A) of the FD&C Act), which provides that no food additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal. The petitioners cite, as evidence, conclusions by the National Toxicology Program, the International Agency for Research on Cancer, and the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment. The petitioners also include results from an observational epidemiology study in humans exposed to styrene and a number of long-term, animal feeding studies conducted on each of the seven additives to support their request. If we determine new data are available that establish these food additives induce cancer, then FDA will amend § 172.515 to no longer provide for their use by publishing an amendment to the regulation in the **Federal Register**, as set forth in §§ 171.130 and 171.100 (21 CFR 171.100).

Although the petition proposes to amend only § 172.515 to no longer provide for the use of these seven synthetic flavoring substances, our action in response to the petition could affect other regulations which provide specifically for the use of these additives. Specifically, benzophenone is also approved for use as an indirect food additive, *i.e.*, a plasticizer (21 CFR 177.2600(c)(4)(iv) diphenyl ketone). We note that some of these flavoring substances (*e.g.*, ethyl acrylate, pyridine, styrene) are permitted for use by other food additive regulations and food contact notifications as reactants or manufacturing aids. Such uses are not the subject of these food additive regulations and food contact notifications, and as such, may not necessarily be affected if this petition results in a regulation.

III. Establish a Zero Tolerance

The petition also requests that FDA explicitly establish a zero tolerance for these seven substances in § 172.515. There is no statutory or regulatory provision for establishing a zero tolerance standard for flavoring food additives in § 172.515. We note, however, that 21 CFR part 189 permits FDA to prohibit by rulemaking the use of substances in human foods because of a determination that they present a potential risk to the public health or have not been shown by adequate scientific data to be safe for use in human foods. To the extent that a rulemaking under part 189 to prohibit the use of these seven substances in food satisfies the petitioner's request for a zero tolerance, we will consider, to the extent appropriate, whether such a rulemaking is necessary if this petition results in a regulation.

We also are reviewing the potential environmental impact of the petitioners' requested action. The petitioners have claimed a categorical exclusion from preparing an environmental assessment or environmental impact statement

under 21 CFR 25.32(m). In accordance with regulations issued under the National Environmental Policy Act (40 CFR 1506.6(b)), we are placing the environmental document submitted with the subject petition on public display at the Division of Dockets Management (see **ADDRESSES**) so that interested persons may review the document. If we determine that the petitioners' claim of categorical exclusion is warranted and that neither an environmental assessment nor an environmental impact statement is required, we will announce our determination in the **Federal Register** if this petition results in a regulation. If we determine that the claim of categorical exclusion is not warranted, we will place the environmental assessment on public display at the Division of Dockets Management and provide notice in the **Federal Register** announcing its availability for review and comment.

Dated: December 29, 2015.

Dennis M. Keefe,

Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. 2015–33011 Filed 12–31–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF STATE

22 CFR Part 147

[Public Notice: 9390]

RIN 1400–AD87

Electronic and Information Technology

AGENCY: Department of State.

ACTION: Proposed rule.

SUMMARY: This proposed rule implements Section 508 of the Rehabilitation Act (Section 508) for the Department of State. Section 508 requires that Federal departments and agencies shall ensure accessibility by individuals with disabilities who are Federal employees, applicants for employment, or members of the public when developing, procuring, maintaining, or using electronic and information technology.

DATES: You may submit comments by March 4, 2016.

ADDRESSES: Interested parties may submit comments by one of the following methods:

- *Email: kottmyeram@state.gov* with the subject line, "Section 508 proposed rule."
- *Internet:* At *www.regulations.gov*, search for this notice by searching for Docket No. DOS–2015–0072 or by the rule's RIN (1400–AD87).
- *By mail:* Office of the Legal Adviser for Management, ATTN: Section 508 Rule, Room 4325, 2201 C Street NW., Washington, DC 20520.

Comments received outside of the comment period may be considered if feasible, but consideration cannot be assured. Those submitting comments to *www.regulations.gov* should not include any personally identifying information or information for which a claim of confidentiality would be asserted; the Department of State will not remove or mask any information from comments that are posted at *www.regulations.gov*. Parties who wish to comment anonymously may do so by submitting their comments via *www.regulations.gov*, leaving the fields that would identify the commenter blank and including no identifying information in the comment itself. Comments submitted via *www.regulations.gov* are immediately available for public inspection.

FOR FURTHER INFORMATION CONTACT: Alice Kottmyer, Attorney-Adviser, 202–647–2318, *kottmyeram@state.gov* (please use the subject line: "Section 508 proposed rule").

SUPPLEMENTARY INFORMATION: The purpose of this proposed rule is to add a new part 147, which implements Section 508 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 794d) ("Section 508"), as it applies to programs and activities conducted by the Department of State ("the Department"). The title of this proposed rule reflects that it applies to Electronic and Information Technology (EIT). Some authorities cited in this rulemaking might use the term "Information and Communications Technology" or "ICT." For the purposes of this rulemaking, the Department considers "EIT" and "ICT" to be interchangeable.

Subpart A—General Provisions

Proposed §§ 147.1 and 147.2 provide that these proposed rules are intended to implement Section 508, consistent with that statute and the regulations promulgated by the Access Board, at 36 CFR part 1194 ("Part 1194"). This proposed rule applies to all development, procurement, maintenance, and use of electronic and information technology by the Department of State. Section 147.3 provides the definitions of "The Department," "Electronic and Information Technology (EIT)", "Section 508," "undue burden," "Section 508 complaint", "the Secretary," and otherwise adopts the definitions in 36 CFR 1194.4.

Section 147.4 provides that the Department will ensure that its employees and applicants for employment are provided with adequate notice of the Department's obligations under Section 508, part 1194, and these rules.

Sections 147.5 and 147.6 generally reiterate the requirements of Section 508 regarding the prohibition against discrimination, and the requirement for ensuring that EIT is accessible (in accordance with part 1194), unless an undue burden would be imposed on the Department—in which case an alternative means of access must be provided.

Subpart B—Complaint Procedures

Section 147.7 provides procedures for filing a complaint under Section 508. The procedures included therein are substantially the same procedures the Department has established in implementing Section 504 of the Rehabilitation Act (22 CFR part 144). The relevant procedures are repeated in this rulemaking, for convenience. Any complaint must be filed with the Department's Office of Civil Rights, must be in writing, and submitted by fax, email, mail, or hand-delivery. The final, approved complaint form will be accessible and fillable and will be included for download on the following page: *http://eforms.state.gov/searchform.aspx*. Prior to approval by the Office of Information and Regulatory Affairs, a static version of the form (in PDF format) will be available upon request; see the **FOR FURTHER INFORMATION CONTACT** section above. The Department's analysis and notice pursuant to the Paperwork Reduction Act is included in the "Regulatory Analysis," below. This form will be used for complaints not only under Section 508, but under other statutes as well. This is reflected in the Paperwork Reduction Act analysis, below.

An individual with a disability alleging a violation of Section 508 must file a complaint not later than 180 days after the date the complainant knew, or should have known, of the alleged violation of Section 508. Once the Department receives the complaint, it must conduct an investigation and, within 180 days of receiving the complaint, shall notify the complainant of the results of the investigation in a letter containing findings of fact and conclusions of law; a description of a remedy for each violation found; and a notice of the right to appeal within 90 days of the complainant's receipt from the Department of the notice. The Department will notify the complainant

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