

Data Universal Numbering System number; and point of contact name, mailing address, and telephone and Fax numbers, as applicable. It also addresses the time required for manufacturers and importers to report their product information by entering certain testing information into the electronic or paper forms.

The product information includes: Brand and subbrand name; unique product identification number; type of product identification number; product category and subcategory; and mean weight and standard deviation of tobacco in product.

We estimate that the burden to enter both the company and product information is no more than 1.82 hours for cigarettes, 0.43 hours for RYO, and 0.63 hours for smokeless tobacco products regardless of whether the paper or electronic Form FDA series 3787 is used. The time to report per tobacco product types varies because the number of HPHCs varies by tobacco product category.

The estimated number of responses under section 904(c)(1) is based on FDA's experience and the past 3 years' actual responses to FDA under this provision of the FD&C Act for statutorily regulated products.

Section 2 of table 1 estimates that 88 respondents (46 cigarette filler and RYO tobacco manufacturers and importers and 42 smokeless manufacturers) will test quantities of HPHCs in an average of 24.5 products annually. This section addresses the time required for manufacturers and importers (or their agents) who must test HPHC quantities in products. The burden estimates include the burden to test the tobacco products, draft testing reports, and submit the report to FDA. The total expected burden for this section is 291 hours.

Section 3 of table 1 addresses the time required for manufacturers and importers to test quantities for HPHCs in cigarette smoke. The burden estimates include: The burden to test the number of replicate measurements; test date range; manufacture date range; extraction method; separation method; detection method; and mean quantity and standard deviation of HPHCs and includes the burden to test the tobacco products, draft testing reports, and submit the report to FDA. The annual burden reflects our estimate of the time it takes to test the tobacco products (*i.e.*, carry out laboratory work). The burden estimate assumes that manufacturers and importers report HPHC quantities in cigarette mainstream smoke according to the two smoking regimens. The total

expected burden is 2,128 hours for this section.

The total estimated burden for this information collection is 2,516 hours and 139 responses.

Our estimated burden for the information collection reflects an overall decrease of 2,125 hours and a corresponding decrease of 142 responses. We attribute this decrease to updated information on the number of submissions we received over the last few years.

Dated: May 29, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-11526 Filed 6-3-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-D-2131]

Evaluating Alternate Curricula for the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled "Evaluating Alternate Curricula for the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption." The draft guidance, when finalized, will provide recommendations on the factors that covered farms should consider if they are selecting an alternate curriculum training to meet the requirements of the "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" (Produce Safety Rule) and for educators when developing or evaluating alternate curricula.

DATES: Submit either electronic or written comments on the draft guidance by October 2, 2019 to ensure that the Agency considers your comment on the draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://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 <https://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):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, 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-2019-D-2131 for "Evaluating Alternate Curricula for the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: Guidance for Industry." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff 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 <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. 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: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Fazila Shakir, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1355.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled “Evaluating Alternate Curricula for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: Guidance for Industry.” We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115).

The draft guidance, when finalized, will represent the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

The Produce Safety Rule established science-based minimum standards for the safe growing, harvesting, packing, and holding of produce grown for human consumption. Subpart C of the rule includes the specific requirements for personnel qualifications and training, including the requirement for at least one supervisor or responsible party from a farm to successfully complete food safety training at least equivalent to that received under the standardized curriculum recognized as adequate by FDA (§ 112.22(c) (21 CFR 112.22(c))). For farms covered by the Produce Safety Rule, version 1.1 of the standardized curriculum developed by the Produce Safety Alliance is adequate as the standardized curriculum in § 112.22(c). The purpose of this draft guidance is to provide recommendations on the factors that covered farms should consider if they are using an alternate curriculum training to satisfy the requirements of § 112.22(c) and for educators when developing or evaluating alternate curricula.

II. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/guidance-documents-regulatory-information-topic-food-and-dietary-supplements> or <https://www.regulations.gov>. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: May 29, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-1262]

Notice of Approval of Product Under Voucher: Rare Pediatric Disease Priority Review Voucher

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of approval of a product redeeming a priority review voucher. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the issuance of vouchers as well as the approval of products redeeming a voucher. FDA has determined that MAYZENT (siponimod) approved March 26, 2019, meets the redemption criteria.

FOR FURTHER INFORMATION CONTACT:

Althea Cuff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-4061, Fax: 301-796-9858, email: althea.cuff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will report the issuance of rare pediatric disease priority review vouchers and the approval of products for which a voucher was redeemed. FDA has determined that MAYZENT (siponimod), approved March 26, 2019, meets the redemption criteria.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to <https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseases/Conditions/RarePediatricDiseasePriorityVoucherProgram/default.htm>. For further information about MAYZENT (siponimod) approved March 26, 2019, go to the “Drugs@FDA” website at <https://www.accessdata.fda.gov/scripts/cder/daf/>.

Dated: May 29, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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