ucm126461.htm). The applicants and other holders of approved applications for pemoline products ceased marketing the products at that time.

On August 10, 2018, the applicants listed in the table below requested that FDA withdraw approval of the pemoline ANDAs listed in the table under § 314.150(d) (21 CFR 314.150(d)), and, in doing so, waived their opportunity for a hearing. For the reasons discussed above, which the applicants do not dispute in their withdrawal request letters, and pursuant to the applicants' requests, FDA is withdrawing approval of the ANDAs listed in the table, and all amendments and supplements thereto, under § 314.150(d). Tablet strengths listed in the table below include all strengths FDA has identified as being previously approved under these ANDAs. In each case, approval of the entire application is withdrawn, including any strengths inadvertently missing from the table. Distribution of these products in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d), respectively).

Application No.	Drug	Applicant
ANDA 075030	Pemoline Tablets, 18.75 mg, 37.5 mg, and 75 mg	Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 075287	Pemoline Tablets, 18.75 mg, 37.5 mg, and 75 mg	Watson Laboratories, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 075555	Pemoline Chewable Tablets, 37.5 mg	Teva Pharmaceuticals USA, Inc.
ANDA 075595	Pemoline Tablets, 18.75 mg, 37.5 mg, and 75 mg	Actavis Elizabeth LLC, 425 Privet Rd., Horsham, PA 19044.
ANDA 075678	Pemoline Chewable Tablets, 37.5 mg	Do.

Dated: May 29, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–11519 Filed 6–3–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0049]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by July 5, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0732. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act

OMB Control Number 0910–0732—Extension

The Family Smoking Prevention and Tobacco Control Act (Pub. L. 111–31) (Tobacco Control Act), enacted on June 22, 2009, amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) and provided FDA with the authority to regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own (RYO) tobacco, and smokeless tobacco products to protect the public health and to reduce tobacco use by minors. The Tobacco Control Act also gave FDA the authority to issue regulations deeming other products that meet the statutory definition of a tobacco product to be subject to chapter IX of the FD&C Act (section 901(b) of the FD&C Act (21 U.S.C. 387a(b))).

In accordance with that authority, on May 10, 2016, FDA issued a final rule deeming all products that meet the statutory definition of tobacco product, except accessories of newly deemed tobacco products, to be subject to FDA's tobacco product authority (final deeming rule) (81 FR 28974).

Chapter IX of the FD&C Act now applies to newly regulated products, including sections 904(a)(3) and (c)(1) (21 U.S.C. 387d(a)(3) and (c)(1)). Section 904(a)(3) of the FD&C Act requires the submission of an initial report from each tobacco product manufacturer or importer, or agents thereof, listing all constituents, including smoke constituents as applicable, identified as a harmful and potentially harmful constituent (HPHC) to health by FDA. Reports must be by brand and by quantity in each brand and subbrand. We note that for cigarettes, smokeless tobacco, cigarette filler, and RYO tobacco products, this initial reporting was completed in 2012.

Section 904(c)(1) of the FD&C Act provides that manufacturers of tobacco products not on the market as of June 22, 2009, must also provide the information reportable under section 904(a)(3) at least 90 days prior to introducing the product into interstate commerce.[1]

FDA has taken several steps to identify HPHCs to be reported under section 904 of the FD&C Act, including issuing a guidance discussing FDA's current thinking on the meaning of the

[1] Note that section 904(c)(1) testing and reporting requirements are separate from the requirements that must be satisfied before a new tobacco product (sections 905 and 910 of the FD&C Act (21 U.S.C. 387e and 387j)), or modified risk tobacco product (section 911 of the FD&C Act (21 U.S.C. 387k)) may be marketed.

term ''harmful and potentially harmful constituent'' in the context of implementing the HPHC list requirement under section 904(e) of the FD&C Act (76 FR 5387, January 31, 2011, revised guidance issued August 2016). The guidance is available on the internet at *https://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm241339.htm.* The current established list of HPHCs also is available on the internet at *https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM297828.pdf* (77 FR 20034, April 3, 2012).

The purpose of the information collection is to collect statutorily mandated information regarding HPHCs in tobacco products and tobacco smoke, by brand and by quantity in each brand and subbrand.

To facilitate the submission of HPHC information, Forms FDA 3787a, 3787b, and 3787c for cigarettes, smokeless tobacco products, and RYO tobacco products, respectively, in both paper and electronic formats, are available. Additionally, FDA is developing forms to facilitate the submission of HPHC information for the newly deemed tobacco products. We intend to model these forms on the current HPHC reporting forms (*i.e.,* Forms FDA 3787a, 3787b, and 3787c). A proposed information collection for newly deemed products will be published in a separate **Federal Register** notice, and we will solicit comments on that collection at that time.

Manufacturers or importers, or their agents, may submit HPHC information either electronically or in paper format. The FDA eSubmitter tool provides electronic forms to streamline the data entry and submission process for reporting HPHCs for cigarettes, smokeless tobacco products, and RYO tobacco products. Users of eSubmitter may populate an FDA-created Excel file and import data into eSubmitter. Whether respondents decide to submit reports electronically or on paper, each form provides instructions for completing and submitting HPHC information to FDA. The forms contain fields for company information, product information, and HPHC information.

In the **Federal Register** of January 31, 2019 (84 FR 744), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received one comment that referenced ingredient reporting; however, that comment is nonresponsive to this information collection, which specifically covers HPHCs. FDA notes that this information collection relates to section 904(a)(3) of the FD&C Act, which requires each tobacco product manufacturer or importer, or an agent, to report a listing of all constituents, including smoke constituents as applicable, identified by FDA as harmful or potentially harmful to health in each tobacco product, and as applicable in the smoke of each tobacco product.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Reporting for Section 904(c)(1) Products					
1. Reporting of Manufacturer/Importer Company and Product Information by Completing Submission Forms					
Cigarette	67	0.67	45	1.82	82
RYO	46	0.033	1.5	0.43	1
Smokeless	42	0.54	23	0.63	14
Total					97
2. Testing of HPHC Quantities in Products					
Cigarette Filler and RYO	46	0.033	1.5	9.42	14
Smokeless	42	0.54	23	12.06	277
Total					291
3. Testing of HPHC Quantities in Mainstream Smoke					
Cigarette: ISO Regimen	67	0.67	45	23.64	1,064
Cigarette: Health Canada Regimen	67	0.67	45	23.64	1,064
Total					2,128
Total Section 904(c)(1) Reporting Burden Hours					2,516

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden for this collection of information is estimated to be 2,516 hours. The burden estimate for this collection of information includes the time it will take to read the instructions, test the products, and prepare the HPHC report.

In arriving at this burden estimate, FDA estimated the number of tobacco products to be reported under the requirements of section 904(c)(1) of the FD&C Act annually to FDA.

Section 1 of table 1 estimates that 155 respondents (67 cigarette manufacturers or importers, 46 RYO tobacco manufacturers, 42 smokeless manufacturers) will submit 97 HPHC reports annually. This section addresses the time required for manufacturers and importers (or their agents), who must report their product information to FDA under section 904(c)(1) of the FD&C Act at least 90 days prior to delivery for introduction into interstate commerce for all new products, to report their company information to FDA through the use of the electronic portal or paper forms.

The company information reported includes: Company name; mailing address; telephone and Fax numbers; FDA Establishment Identifier number;

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]

BILLING CODE 4164–01–P

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