DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–6644]

Fiscal Year 2020 Generic Drug Regulatory Science Initiatives; Public Workshop; Remote Only

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration is announcing that the following public workshop entitled ''FY 2020 Generic Drug Regulatory Science Initiatives'' announced in the **Federal Register** on March 10, 2020, is being modified to take place remotely.

DATES: The public workshop will be held on May 4, 2020, from 8:30 a.m. to 4:30 p.m. Submit either electronic or written comments on this public workshop by June 4, 2020. See the **SUPPLEMENTARY INFORMATION** section for registration and participation information.

FOR FURTHER INFORMATION CONTACT: Stephanie Choi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4732, Silver Spring, MD 20993–0002, 240–402–7960, *Stephanie.Choi@fda.hhs.gov;* or Robert Lionberger, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4722, Silver Spring, MD 20993, 240–402–7957, *Robert.Lionberger@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Due to the ongoing COVID–19 pandemic, this workshop announced in the **Federal Register** on March 10, 2020 (85 FR 13905) is being changed from in person to remote only. How to register and participate in this remote meeting will be communicated on the FDA web page at the following address: *https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/fy-2020-generic-drug-regulatory-science-initiatives-public-workshop-05042020-05042020.*

Dated: April 24, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–09168 Filed 4–29–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–2834]

Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule; Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the withdrawal of a guidance for industry entitled ''Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule,'' which was issued in 2017. The guidance was intended to assist persons who manufacture, package, sell, offer to sell, distribute, or import for sale and distribution within the United States newly regulated tobacco products, roll-your-own (RYO) tobacco, and cigarette tobacco in complying with the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), and FDA regulations. FDA is withdrawing the guidance because the compliance deadlines contained therein have passed, have been vacated or stayed, or are otherwise described in other guidance.

DATES: The withdrawal is applicable April 30, 2020.

FOR FURTHER INFORMATION CONTACT: Eric C. Mandle, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Document Control Center, Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002; 1–877–287–1373, *CTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is withdrawing the guidance for industry entitled ''Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule,'' which was issued in 2017 (see 82 FR 37459 (August 10, 2017)) and which has been revised several times since then. The guidance was intended to assist persons who manufacture, package, sell, offer to sell, distribute, or import for sale and distribution within the United States newly regulated tobacco products, RYO tobacco, and cigarette tobacco in complying with the FD&C Act, as amended by the Tobacco Control Act, and FDA regulations.

The Tobacco Control Act (Pub. L. 111–31) granted FDA the authority to immediately regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, RYO, 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 a regulation deeming all 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) (21 U.S.C. 387a(b)) of the FD&C Act). On May 10, 2016, FDA issued that rule, extending FDA's tobacco product authority to all products that meet the definition of tobacco product in the law (except for accessories of newly regulated tobacco products), including electronic nicotine delivery systems, cigars, hookah, pipe tobacco, nicotine gels, dissolvables that were not already subject to the FD&C Act, and other tobacco products that may be developed in the future (81 FR 28974 at 28976) (''the final deeming rule'').

In May 2017, FDA published the first edition of this guidance, under which it provided a 3-month extension of all future compliance deadlines under the final deeming rule. The second edition of the guidance, published in August 2017, revised and updated the first edition by further extending certain of the future compliance dates.

On May 15, 2019, the U.S. District Court for the District of Maryland issued an order vacating the extended compliance dates for premarket review in the guidance.[1] On July 12, 2019, the court issued an order directing FDA to require that premarket authorization applications for all new—*i.e.,* not ''grandfathered'' [2]—deemed tobacco products to be submitted to the Agency within 10 months, by May 12, 2020, and providing for a 1-year period during which products with timely filed applications might remain on the market pending FDA review.[3] As

[1] *American Academy of Pediatrics, et al.* v. *Food and Drug Administration, et al.,* 379 F.Supp.3d 461 (D. Md. 2019).

[2] A ''grandfathered'' product is one that was on the market as of February 15, 2007. ''Guidance for Industry, Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007,'' dated September 2014, available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/establishing-tobacco-product-was-commercially-marketed-united-states-february-15-2007.*

[3] *American Academy of Pediatrics, et al.* v. *Food and Drug Administration, et al.,* 399 F.Supp.3d 479 (D. Md. 2019). The court has granted intervention to vapor industry trade associations for purposes of appealing the court's decision and remedies order. *See American Academy of Pediatrics, et al.* v. *Food and Drug Administration, et al.,* No. 8:18–cv–883

required by the court's order, deemed new tobacco products on the market as of August 8, 2016, for which premarket authorization applications are not filed by May 12, 2020, are subject to FDA enforcement actions, in the Agency's discretion. The court subsequently clarified that its order did not restrict FDA's authority to enforce the premarket review provisions against deemed products, prior to May 12, 2020, or during the 1-year review period.[4] On April 22, 2020, the court, upon FDA's motion, extended the premarket application deadline set out in its order by 120 days (until September 9, 2020) in light of the global outbreak of respiratory illness caused by a new coronavirus.[5]

FDA is withdrawing the guidance because the compliance deadlines contained therein have passed, have been vacated, or are stayed, with the exception of those for reporting requirements for harmful or potentially harmful constituents (HPHC). FDA has published and described these deadlines in the Small Entity Compliance Guide for the final deeming rule;[6] they are also listed on the Center for Tobacco Products' HPHC website.[7]

Dated: April 24, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–09163 Filed 4–29–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0597]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Index of Legally Marketed Unapproved New Animal Drugs for Minor Species

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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: Submit written comments (including recommendations) on the collection of information by June 1, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0620. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *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.

Index of Legally Marketed Unapproved New Animal Drugs for Minor Species—21 CFR Part 516

OMB Control Number 0910–0620—Extension

The Minor Use and Minor Species Animal Health Act of 2004 (the MUMS Act) (Pub. L. 108–282) added section 572 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360ccc–1), which authorizes FDA to establish new regulatory procedures intended to make more medications legally available to veterinarians and animal owners for the treatment of minor animal species (species other than cattle, horses, swine, chickens, turkeys, dogs, and cats). In enacting the MUMS Act, Congress sought to encourage the development of these new animal drugs. Congress recognized that the markets for drugs intended to treat these species are so small that there are often insufficient economic incentives to motivate drug companies to develop data to support approvals. Further, Congress recognized that some minor species populations are too small or their management systems too diverse to make it practical to conduct traditional studies to demonstrate safety and effectiveness of animal drugs for such uses.

As a result of these limitations, drug companies have generally not been willing or able to collect data to support legal marketing of drugs for these species. Consequently, Congress enacted the MUMS Act to provide incentives to develop new animal drugs for minor species, while still ensuring appropriate safeguards for animal and human health. Section 572 of the FD&C Act provides for a public index listing of legally marketed unapproved new animal drugs for minor species. FDA regulations in part 516 (21 CFR part 516) specify, among other things, the criteria and procedures for requesting eligibility for indexing and for requesting addition to the index, as well as the annual reporting requirements for index holders. The administrative procedures and criteria for indexing a new animal drug for use in a minor species are set forth in §§ 516.111 through 516.171 (21 CFR 516.111 through 516.171). Section 516.165 sets forth the annual reporting requirements for index holders. FDA needs the information to determine: (1) The eligibility of a new animal drug for indexing; (2) that a qualified expert panel proposed to review certain information regarding the new animal drug meets the selection criteria listed in the regulations; (3) whether the Agency agrees with the recommendation of a qualified expert panel that a drug be added to the index; and (4) whether there may be grounds for removing a drug from the index.

In the **Federal Register** of January 7, 2020 (85 FR 714), we published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four collection of information topics solicited.

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

(PWG), Dkt. No. 154 (October 2, 2019). An appeal is pending. *See American Academy of Pediatrics* v. *Cigar Ass'n of America,* Nos. 19–2130, –2132, –2198 (4th Cir.).

[4] *American Academy of Pediatrics, et al.* v. *Food and Drug Administration, et al.,* Case No. 8:18–cv–883 (PWG), (D. Md. August 12, 2019), Dkt. No. 132.

[5] *American Academy of Pediatrics, et al.* v. *Food and Drug Administration, et al.,* Case No. 8:18–cv–883 (PWG), (D. Md. April 22, 2020), Dkt. No. 182.

[6] *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-deems-certain-tobacco-products-subject-fda-authority-sales-and-distribution-restrictions-and.*

[7] For more information, please see *https://www.fda.gov/tobacco-products/products-ingredients-components/harmful-and-potentially-harmful-constituents-hphcs.*