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]

BILLING CODE 4164–01–P

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.*

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
516.119; requires a foreign drug company to submit and update the name and address of a permanent U.S. resident agent	5	1	5	1	5
516.121; written request for a meeting with FDA to discuss the requirements for indexing a new animal drug	30	2	60	4	240
516.123; written request for an informal conference and a requestor's written response to an FDA initial decision denying a request	3	1	3	8	24
516.125; correspondence and information associated with investigational use of new animal drugs intended for indexing	2	3	6	20	120
516.129; content and format of a request for determination of eligibility for indexing	30	2	60	20	1,200
516.141; information to be submitted to FDA by a requestor seeking to establish a qualified expert panel	20	1	20	16	320
516.143; content and format of the written report of the qualified expert panel	20	1	20	120	2,400
516.145; content and format of a request for addition to the index	20	1	20	20	400
516.161; content and format of a request for modification of an indexed drug	3	1	3	4	12
516.163; information to be contained in a request to FDA to transfer ownership of a drug's index file to another person	1	1	1	2	2
516.165; requires drug experience reports and distributor statements to be submitted to FDA	10	10	100	5	500
Total					5,223

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
516.141, requires the qualified expert panel leader to maintain a copy of the written report and all notes or minutes relating to panel deliberations that are submitted to the requestor for 2 years after the report is submitted.	30	2	60	0.5 (30 minutes)	30
516.165, requires the holder of an indexed drug to maintain records of all information pertinent to the safety or effectiveness of the indexed drug, from foreign and domestic sources.	10	2	20	1	20
Total					50

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

We based our estimates in tables 1 and 2 on our experience with the MUMS indexing program and the requests for eligibility for indexing and for addition to the index, as well as the periodic drug experience reports submitted during the past 3 years.

Our estimated burden for the information collection reflects an overall increase of 351 reporting hours and a corresponding increase of 85 responses. We attribute this adjustment, generally, to an increase in the number of submissions we received over the last few years. We also reduced our burden hour estimate for drug experience reports and distributor statements under § 516.165 from 8 hours per submission to 5 hours per submission based on our experience with this type of reporting.

Dated: April 23, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–09170 Filed 4–29–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0008]

Ophthalmic Devices Panel of the Medical Devices Advisory Committee: Notice of Meeting; Postponement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting; postponement.

SUMMARY: The Food and Drug Administration (FDA) is postponing the