Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: *Regarding tracers used in animal food:* Diego Paiva, Center for Veterinary Medicine (HFV–229), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–6785, *Diego.Paiva@fda.hhs.gov.*

Regarding tracers used in animal drug products: Rebecca Owen, Center for Veterinary Medicine (HFV–141), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0670, *Rebecca.Owen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 2, 2022 (87 FR 11719), FDA published the notice of availability for a draft GIF #258 entitled ''Use of Tracers in Animal Food, Type A Medicated Articles, and Medicated Feeds'' giving interested persons until May 2, 2022, to comment on the draft guidance. FDA received one comment submission on the draft guidance and the comments in that submission were considered as the guidance was finalized. The guidance announced in this notice finalizes the draft guidance dated March 2, 2022. This guidance replaces CPG Sec. 680.100 ''Tracers in Animal Feed.''

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on the use of tracers in animal food, Type A medicated articles, and medicated feeds. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR 501.22 have been approved under OMB control number 0910–0721. The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: October 14, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–22705 Filed 10–18–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–2854]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Premarket Tobacco Product Applications and Recordkeeping Requirements

AGENCY: Food and Drug Administration, Health and Human Services (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 November 18, 2022.

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 0910–0879.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *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.

Premarket Tobacco Product Applications and Recordkeeping Requirements—21 CFR 1114

OMB Control Number 0910–0879—Extension

This information collection supports the requirements for the content, format, submission recordkeeping, and postmarket reporting requirements of a premarket tobacco product application (PMTA). Section 910(a) (21 U.S.C. 387j(a)) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) established requirements for premarket review of new tobacco products and the implementing regulations are found in part 1114 (21 CFR part 1114), subchapter K.

An applicant may submit a PMTA to demonstrate that a new tobacco product meets the requirements to receive a marketing granted order. A new tobacco product may not be introduced or delivered for introduction into interstate commerce under this part until FDA has issued a marketing granted order for the product (§ 1114.5). Further, § 1114.7 describes the required content and format of the PMTA. The PMTA must contain sufficient information for FDA to determine whether any of the grounds for denial specified in section 910(c)(2) of the FD&C Act apply. The application must contain the following sections: general information, descriptive information, product samples, labeling, a statement of compliance with 21 CFR part 25, a summary, product formulation, manufacturing, health risk investigations, effect on the population as a whole, and a certification statement.

Submitters can visit the following web page which describes the process for submitting a PMTA (*https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/premarket-tobacco-product-applications*).

After submission of a PMTA, FDA may request, and an applicant may submit, an amendment to a pending PMTA. FDA generally expects that when an applicant submits a PMTA, the submission will include all information required by section 910(b)(1) of the FD&C Act and part 1114 to enable FDA to determine whether it should authorize the marketing of a new tobacco product. However, FDA recognizes that additional information

may be needed to complete the review of a PMTA and, therefore FDA allows the submission of amendments to a pending application.

An applicant may transfer ownership of its PMTA at any time, including when FDA has yet to act on it. Section 1114.13 describes the steps that an applicant would be required to take when it changes ownership of a PMTA. This section is intended to facilitate transfers of ownership and help ensure that FDA has current information regarding the ownership of a PMTA.

A supplemental PMTA are an alternative format of submitting a PMTA (§ 1114.15). Applicants that have received a marketing granted order would be able to submit a supplemental PMTA to seek marketing authorization for a new tobacco product that results from a modification or modifications to the original tobacco product that received the marketing granted order. FDA restricts the use of supplemental PMTAs to only changes that require the submission of limited information or revisions to ensure that FDA can efficiently review the application.

If an applicant receives a no marketing granted order, they may submit a resubmission to respond to the deficiencies outlined (§ 1114.17). A resubmission may be submitted for the same tobacco product that received a marketing denial order or for a different new tobacco product that results from changes necessary to address the deficiencies outlined in a marketing denial order. This application format allows an applicant to address the deficiencies described in a marketing denial order without having to undertake the effort of submitting a standard PMTA. The resubmission format is not available for PMTAs that FDA refused to accept, refused to file, cancelled, or administratively closed, or that the applicant withdrew because FDA has not previously completed reviews of such applications upon which it can rely, and such applications may need significant changes to be successfully resubmitted.

FDA requires applicants that receive a marketing granted order to submit postmarket reports. Postmarket reports determine or facilitate a determination of whether there may be grounds to withdraw or temporarily suspend a marketing granted order. Applicants are required to submit two types of postmarket reports after receiving a marketing granted order: periodic reports and adverse experience reports. Periodic reports are required to be submitted within 60 calendar days of the reporting date specified in the marketing granted order. Applicants would also be required to report all serious and unexpected adverse experiences associated with the tobacco product that have been reported to the applicant or of which the applicant is aware. The serious and unexpected adverse experience reports must be submitted to the Center for Tobacco Products' Office of Science through the HHS Safety Reporting Portal (*https://www.safetyreporting.hhs.gov/*) within 15 calendar days after receiving or becoming aware of a serious or unexpected adverse experience. FDA's Safety Reporting Portal is approved under OMB control number 0910–0291.

Applicants receiving a marketing granted order are required to maintain all records necessary to facilitate a determination of whether there are or may be grounds to withdraw or temporarily suspend the marketing granted order, including records related to both the application and postmarket reports, and ensure that such records remain readily available to the Agency upon request (§ 1114.45).

The Consolidated Appropriations Act of 2022 (the Appropriations Act), enacted on March 15, 2022, amended the definition of the term ''tobacco product'' in section 201(rr) (U.S.C. 321(rr)) of the FD&C Act to include products that contain nicotine from any source. As a result, non-tobacco nicotine (NTN) products that were not previously subject to the FD&C Act (*e.g.,* products containing synthetic nicotine) are now subject to all of the tobacco product provisions in the FD&C Act beginning on April 14, 2022, including the requirement of premarket review for new tobacco products. The Appropriations Act also makes all rules and guidances applicable to tobacco products apply to NTN products on that same effective date, which includes the Premarket Tobacco Product Application and Recordkeeping Requirements final rule. Additionally, the Appropriations Act includes a transition period for premarket review requirements, directing companies to submit PMTAs for NTN products by May 14, 2022, to receive an additional 60-day period of marketing without being considered in violation of premarket review requirements. On April 14, 2022, OMB granted an emergency clearance under this collection to include NTN products and its associated burden. OMB granted a 6-month approval, and as such per the requirements of the PRA, the Agency is seeking comment on these new estimates.

In the **Federal Register** of May 16, 2022 (87 FR 29749), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR part; activity; form FDA #	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
1114.5; Submission of Standard Bundled PMTAs [2]	1	1	1	1,713	1,713
PMTA Submission; Form FDA 4057	39	1	39	0.75 (45 minutes).	29
PMTA Amendment and General Correspondence Submission; Form FDA 4057a.	39	14	546	0.16 (10 minutes).	87
PMTA Grouping Submission; Form FDA 4057b	39	1	39	0.75 (45 minutes).	29
1114.41; Reporting Requirements (periodic reports)	4	1	4	50	200
1114.9; Amendments	24	2	48	188	9,024
1114.13; Change in Ownership	1	1	1	1	1
1114.15; Supplemental Applications	2	1	2	428	856
1114.17; Resubmissions	3	1	3	565	1,695
1114.41(a)(2); Adverse Experience Reports	4	6	24	1	24
1114.49(b) and (c); Waiver from Electronic Submission	1	1	1	0.25 (15 minutes).	0.25

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR part; activity; form FDA #	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Total					13,658

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] FDA anticipates that applicants will submit bundled PMTAs, which are single submissions containing PMTAs for a number of similar or related products. We estimate that a bundle will contain on average between 6 and 11 distinct products.

Table 1 describes the estimated annual reporting burden. FDA has based these estimates on the full analysis of economic impacts and experience with current PMTA submissions received under OMB control number 0910–0768 (which covers the burden for electronic nicotine delivery system (ENDS) products PMTA submissions). This average represents a wide range of hours that will be required for these applications under different circumstances, with some requiring more hours (*e.g.,* as many as 5,000 hours for early applications that involve complex products and for which the company has no experience conducting studies or preparing analysis of public health impacts, or for which reliance on master files is not possible) as well as many requiring fewer hours (*e.g.,* as few as 50 hours for applications for products that are very similar to other new products). FDA estimates that it will take each respondent approximately 1,500 hours to prepare a PMTA seeking an order from FDA allowing the marketing of a new tobacco product. FDA also estimates that it would on average take an additional 213 hours to prepare an environmental assessment (EA) in accordance with the requirements of 21 CFR 25.40, for a total of 1,713 hours per PMTA application.

FDA assumes that firms will submit all applications as PMTA bundles. We also considered updated data on market consolidation that has occurred since the Deeming Rule published for originally regulated products that would receive marketing granted orders through the PMTA pathway. For originally regulated products we expect to receive one full PMTA submission for a total of 1,713 hours. We believe that bundling PMTAs results in efficiencies for applicants when compared to submitting standalone, full-text submissions for each product. We expect to receive bundled PMTAs where applicants can use the same evidence to support PMTAs for similar or related products. Bundling PMTAs into a single submission would eliminate the administrative burden of having to reproduce the same evidence in a standalone PMTA for each product.

FDA has three forms for use when submitting PMTA information to the Agency. Form FDA 4057 for use when submitting PMTA single and bundled submissions. FDA estimates that 39 respondents will submit PMTA bundles using this form at 0.75 (45 minutes) per response. The number 39 is accounting for the bundles of ENDS products and includes 15 new expected bundles submitted for NTN products and the 1 bundle we expect to receive yearly for originally regulated products, for a total of 29 hours.

Form FDA 4057a for use when firms are submitting amendments and other general correspondence. FDA estimates that 39 respondents will submit amendments and other general correspondence using this form at 0.16 (10 minutes) per response, including 15 new expected submissions related to applications submitted for NTN products. We estimate there will be at least 14 amendments per application for a total of 87 hours. With most applications being submitted toward the end of our 3-year range, we expect fewer amendments during this period. However, FDA expects correspondence from earlier applications to be submitted during this period.

Form FDA 4057b assists industry and FDA in identifying the products that are the subject of a submission where an applicant groups multiple PMTAs into a single submission (referred to as a bundled submission or a grouped submission). FDA has previously stated that one approach to submitting PMTAs could be to group applications for products that are both from the same manufacturer or domestic importer and in the same product category and subcategory into a single submission. The form assists applicants in providing the unique identifying information for each product in a grouped submission of PMTAs. A respondent would utilize Form FDA 4057b once for each submission containing more than one PMTA. We assume the submitter could include from 2 to 2,000 products in each Form FDA 4057b. Entering data for up to 2,000 rows can take approximately 4 hours on average per Form FDA 4057b for manual data entry. We reflect the average time of 45 minutes per response based on the assumption that we expect to receive an average of nine bundled products per submission. Assuming 45 minutes per Form FDA 4057b for 39 applications, we estimate a total burden of 29 hours for this activity. Included in this estimate are the 15 new expected submissions submitted from NTN products.

FDA estimates under § 1114.41 that four respondents will submit a periodic report. This number is based on the average number of periodic report submissions expected between 2020–2022 and the addition of NTN products. The Agency estimates that periodic reports will take on average of 50 hours per response for a total of 200 hours. Firms must also submit adverse experience reports (§ 1114.41(a)(2)) for tobacco products with marketing orders. We assume the same number of firms submitting periodic reports will submit adverse experience reports. Currently, firms may voluntarily submit adverse experience reports using Form FDA 3800 under OMB control number 0910–0645. We have based our estimates on this information collection which estimates that it takes 1 hour (for mandatory reporting) to complete this form for tobacco products for a total of 24 hours.

Under § 1114.9 firms will prepare amendments to PMTA bundles in response to deficiency letters. These amendments contain additional information that we need to complete substantive review. We anticipate 2 responses back per bundle and therefore, we estimate that 24 respondents will submit 48 amendments (24×2). Assuming 1,500 hours as the time to prepare and submit a full PMTA and amendments may on average take 10 percent to 15 percent of that time (150–225). We averaged this time out (12.5 percent of a full submission preparation time) and arrived at 188 hours per response. FDA estimates the total burden hours for preparing amendments is 9,024 hours.

Section 1114.13 would allow an applicant to transfer ownership of a PMTA to a new owner. FDA believes this will be infrequent, so we have

assigned 1 hour acknowledging the requirement.

Section 1114.15 is an alternative format of submitting a PMTA that meets the requirements of § 1114.7 that would reduce the burden associated with the submission and review of an application. Our estimated number of 2 respondents is based on the number estimated for postmarket reports, which is 4 bundles (which is approximately 34 products). Not all applicants will resubmit modifications to previously authorized products, so we estimate 2 bundles (which is approximately 17 products). FDA estimates further that a supplemental PMTA will take 25 percent of the time it takes to do an original submission (including EA hours) for 428 hours per response. We estimate a total of 856 burden hours for this activity.

Under § 1114.17 an applicant may utilize the resubmission format for the same tobacco product for which FDA issued a marketing denial order or for a new tobacco product that results from changes necessary to address the deficiencies described in a marketing denial order. We are estimating that out of all bundles received in 2020, 2021, and 2022, that an average of three bundles are authorized. If we receive 24 amendments to bundles yearly, we estimate based on historical data, 58 percent fail at acceptance (down to 8 bundles remaining), 17 percent fail at filing (down to 7 bundles remaining), and 25 percent receive marketing orders (5 left). We also estimate that 50 percent of the applications that receive marketing denial orders will try to resubmit in a year. Thus, this number of respondents is three (rounded up). FDA estimates that a resubmission will take 33 percent of the time it takes to complete an original submission (including EA hours) at 565 hours per response for a total of 1,695 hours.

An applicant is required to submit a PMTA and all supporting and related documents to FDA in electronic format that FDA can process, review, and archive unless an applicant requests, and FDA grants, a waiver from this requirement. FDA does not believe we will receive many waivers, so we have assigned one respondent to acknowledge the option to submit a waiver. Consistent with our other application estimates for waivers, we believe it would take .25 hours (15 minutes) per waiver for a total of .25 hours.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR part; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
1114.45; PMTA Records	39	1	39	2	78
1100.204; Pre-existing Products Records	1	1	1	2	2
1107.3; Exemptions From Substantial Equivalence (SE) Records	1	1	1	2	2
Total					82

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

Table 2 describes the annual recordkeeping burden. FDA estimates that 39 recordkeepers will maintain records at 2 hours per record. Included in this estimate are the 15 expected new recordkeepers of NTN products. Firms are also required to establish and maintain records related to SE exemption requests and pre-existing products (§ 1100.200 states that subpart C of part 1100). We expect the burden hours to be negligible for SE exemption requests. Firms would have already established the required records when submitting the SE exemption request. Similarly, we expect the hours of to be negligible for any pre-existing tobacco products that have already submitted standalone pre-existing tobacco product submissions, because firms would have established the required records when submitting the standalone pre-existing tobacco product submissions. We believe this time is usual and customary for these firms. We estimate that it would take 2 hours per record to establish the required records for a total of 4 hours.

Relative to the emergency approval by OMB our estimated burden for the information collection reflects an overall increase of 72 hours and a corresponding increase of 117 responses/records. We attribute this adjustment to the addition of NTN product submissions.

Dated: October 11, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–22708 Filed 10–18–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Neonatal Research Network.

Date: November 7–8, 2022.

Closed: 10:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6710B Rockledge Drive, Room 2140, Bethesda, MD 20892–7510 (Virtual Meeting).

Contact Person: Joanna Kubler-Kielb, Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH 6710B, Rockledge Drive, Room 2140, Bethesda, MD 20892, (301) 435–6916, *kielbj@mail.nih.gov.*

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Neonatal Research Network and Maternal-Fetal Medicine Units Network: Data Coordinating Centers.

Date: November 10, 2022.

Closed: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.