A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, TAUVID (flortaucipir F–18). TAUVID is indicated for positron emission tomography imaging of the brain to estimate the density and distribution of aggregated tau neurofibrillary tangles in adult patients with cognitive impairment who are being evaluated for Alzheimer's disease. Subsequent to this approval, the USPTO received a patent term restoration application for TAUVID (U.S. Patent No. 8,932,557) from Eli Lilly and Company, and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated December 14, 2020, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of TAUVID represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for TAUVID is 3,067 days. Of this time, 2,825 days occurred during the testing phase of the regulatory review period, while 242 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* January 6, 2012. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on January 6, 2012.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* September 30, 2019. FDA has verified the applicant's claim that the new drug application (NDA) for TAUVID (NDA 212123) was initially submitted on September 30, 2019.

3. *The date the application was approved:* May 28, 2020. FDA has verified the applicant's claim that NDA 212123 was approved on May 28, 2020.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,102 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: July 18, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–15679 Filed 7–21–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0377]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Tobacco Health Document Submission

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, 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: Submit written comments (including recommendations) on the collection of information by August 22, 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 0910–0654. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *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.

Tobacco Health Document Submission

OMB Control Number 0910–0654—Revision

Section 904(a)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 387d(a)(4)) requires each tobacco product manufacturer or importer, or agent thereof, to submit all documents developed after June 22, 2009, ''that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke

constituents), ingredients, components, and additives'' (herein referred to as ''tobacco health documents'' or ''health documents'').

The guidance document entitled ''Health Document Submission Requirements for Tobacco Products (Revised)'' (2017) (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/tobacco-health-document-submission*) requests tobacco health document submissions from manufacturers and importers of tobacco products based on statutory requirements and compliance dates.[1] As indicated in the guidance, all manufacturers and importers of tobacco products are now subject to the FD&C Act and are required to comply with section 904(a)(4) of the FD&C Act, which requires immediate and ongoing submission of health documents developed after June 22, 2009 (the date of enactment of the Tobacco Control Act). However, FDA generally does not intend to enforce the requirement at this time with respect to all such health documents, so long as a specified set of documents, those developed between June 23, 2009, and December 31, 2009, are provided at least 90 days prior to the delivery for introduction of tobacco products into interstate commerce. Thereafter, manufacturers should preserve all health documents, including those that relate to products for further manufacturing and those developed after December 31, 2009, for future submission to FDA. All Agency guidance documents are issued in accordance with our good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time.

FDA is planning revisions to the guidance to reflect that the deemed tobacco product compliance period has passed. Additional revisions include clarifying and editorial changes to promote a better understanding of FDA's interpretation of the ''health, toxicological, behavioral, or physiologic'' phrase, examples of health, toxicological, behavioral, or physiologic effects documents, and minor updates to the metadata list.

FDA has been collecting the information submitted pursuant to section 904(a)(4) of the FD&C Act through a facilitative electronic form and through a paper form (Form FDA 3743) for those individuals who choose not to use the electronic method. On both forms, FDA is requesting the following information from firms that have not already reported or still have documents to report:

- Submitter identification
- Submitter type, company name, address, country, company headquarters Dun and Bradstreet D–U–N–S number, and FDA assigned Facility Establishment Identifier (FEI) number
- Submitter point of contact
- Contact name, title, position title, email, telephone, and Fax
- Submission format and contents (as applicable)
- Electronic documents: media type, media quantity, size of submission, quantity of documents, file type, and file software
- Paper documents: quantity of documents, quantity of volumes, and quantity of boxes
- Whether or not a submission is being provided
- Confirmation statement
- Identification and signature of submitter including name, company name, address, position title, email, telephone, and Fax
- Document categorization (as applicable): relationship of the document or set of documents to the following:
  - Health, behavioral, toxicological, or physiological effects
  - Uniquely identified current or future tobacco product(s)
  - Category of current or future tobacco product(s)
  - Specific ingredient(s), constituent(s), component(s), or additive(s)
  - Class of ingredient(s), constituent(s), component(s), or additive(s)
- Document readability and accessibility: keywords; glossary or explanation of any abbreviations, jargon, or internal (*e.g.,* code) names; special instructions for loading or compiling submission.
- Document metadata: date document was created, document author(s), document recipient(s), document custodian, document title or identification number, beginning and ending Bates numbers, Bates number ranges for documents attached to a submitted email, document type, and whether the document is present in the University of California San Francisco's Truth Tobacco Documents database.

You may access the electronic form and paper form on our website, at *https://www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal* and *https://www.fda.gov/media/78652/download,* respectively. In addition to the electronic and paper forms, FDA issued the guidance on this collection to assist persons making tobacco health document submissions. For further assistance, FDA is providing a technical guide, embedded hints, and a web tutorial on the electronic portal.

FDA issued a final rule to deem products meeting the statutory definition of ''tobacco product'' to be subject to the FD&C Act on May 10, 2016 (81 FR 28973), which became effective on August 8, 2016. The FD&C Act provides FDA authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco (RYO), smokeless tobacco, and any other tobacco products that the Agency by regulation deems to be subject to the law. This final rule extended the Agency's ''tobacco product'' authorities to all other categories of products that meet the statutory definition of ''tobacco product'' in the FD&C Act, except accessories of such deemed tobacco products.

For tobacco products subject to the deeming rule, FDA understands ''current or future tobacco products'' to refer to products commercially distributed on or after August 8, 2016, or products in any stage of research or development at any time after August 8, 2016, including experimental products and developmental products intended for introduction into the market for consumer use. For cigarettes, cigarette tobacco, RYO, and smokeless tobacco, FDA understands ''current or future tobacco products'' to refer to products commercially distributed on or after June 23, 2009, or products in any stage of research or development at any time after June 23, 2009, including experimental products and developmental products intended for introduction into the market for consumer use.

In the guidance on this collection, FDA indicated our intent to enforce the requirement at this time with respect to all such health documents relating to the deemed tobacco products, so long as a specified set of documents, those developed between June 23, 2009, and December 31, 2009, were submitted by February 8, 2017, or in the case of small-scale deemed tobacco product manufacturers (small-scale manufacturers), by November 8, 2017 (81 FR 28973 at 29008 and 29009). Additionally, FDA extended the compliance deadlines by an additional 6 months for small-scale manufacturers in the areas impacted by natural disasters to May 8, 2018. Thereafter, FDA's compliance plan requested

[1] FDA announced the availability of a guidance on this collection in the **Federal Register** on April 20, 2010 (75 FR 20606) (revised December 5, 2016 (81 FR 87565)).

deemed manufacturers provide tobacco health document submissions from the specified period, at least 90 days prior to the delivery for introduction into interstate commerce of tobacco products to which the health documents relate. Manufacturers or importers of cigarettes, cigarette tobacco, RYO, or smokeless tobacco products must provide all health documents developed between June 23, 2009, and December 31, 2009, at least 90 days prior to the delivery for introduction of tobacco products into interstate commerce.

After publication of the 60-day notice however, on March 15, 2022, President Biden signed H.R. 2471—the Consolidated Appropriations Act, 2022. As a result, the FD&C Act now includes specific language that makes clear that FDA has the authority to regulate tobacco products containing nicotine from any source, which includes synthetic. On April 14, 2022, firms engaged in the manufacture, preparation, compounding, or processing of tobacco products containing non-tobacco nicotine products (NTN) must therefore provide health documents.

In the **Federal Register** of February 25, 2022 (87 FR 10800), 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]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Tobacco Health Document Submissions and Form FDA 3743	10	3.2	32	50	1,600
Tobacco Health Document Submissions and Form 3743 for Non-Tobacco Nicotine Products (NTN)	100	1	100	2	200
Total					1,800

The number of documents received each year since the original collection period has fallen to less than 5 percent of what was received in the original collection period. FDA expects this is because documents created within the specified period should have already been submitted. The Agency bases this estimate on the total number of tobacco firms it is aware of and its experience with document production and the number of additional documents that have been reported each year since the original estimate of the reporting burden.

FDA estimates that a tobacco health document submission as required by section 904(a)(4) of the FD&C Act, will take approximately 50 hours per submission based on FDA experience. To derive the number of respondents for this provision, FDA assumes that very few manufacturers or importers, or agents thereof, would have health documents to submit. We anticipate documents will be submitted on an annual basis for a total of 10 respondents. FDA estimates the annual reporting burden for these respondents to be 1,600 hours.

As mentioned previously in this document, with the new authority provided to FDA, firms engaged in the manufacture, preparation, compounding, or processing of tobacco products containing NTN must provide health documents. Although these firms are unlikely to have health documents created within the specified period, we are estimating for this extension that we will receive 100 new NTN respondents who will be required to provide a declaration to such effect via Form 3743, which is expected to take 2 hours, for a total 200 burden hours.

Based on a review of the information collection of our current OMB approval, we have increased the burden by 200 hours.

Dated: July 18, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–15727 Filed 7–21–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1584]

Authorization of Emergency Use of Certain Medical Devices During COVID–19; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the issuance of Emergency Use Authorizations (EUAs) (the Authorizations) for certain medical devices related to the Coronavirus Disease 2019 (COVID–19) public health emergency. FDA has issued the Authorizations listed in this document under the Federal Food, Drug, and Cosmetic Act (FD&C Act). These Authorizations contain, among other things, conditions on the emergency use of the authorized products. The Authorizations follow the February 4, 2020, determination by the Secretary of Health and Human Services (HHS) that there is a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves the virus that causes COVID–19, and the subsequent declarations on February 4, 2020, March 2, 2020, and March 24, 2020, that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID–19, personal respiratory protective devices, and medical devices, including alternative products used as medical devices, respectively, subject to the terms of any authorization issued under the FD&C Act. These Authorizations, which include an explanation of the reasons for issuance, are listed in this document, and can be accessed on FDA's website from the links indicated.

DATES: These Authorizations are effective on their date of issuance.

ADDRESSES: Submit written requests for single copies of an EUA to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION**