Premarket Tobacco Product Applications and Recordkeeping Requirements

OMB Control Number 0910-0879

Request for Emergency Processing to Revise OMB Control No. 0910-0879 to Modify Form FDA 4057b

The Food and Drug Administration (FDA or we) is requesting emergency processing for the revision of OMB Control No. 0910-0879 to edit Form FDA 4057b based on amendments to Section 201(rr) of the Federal Food, Drug, and Cosmetic (FD&C) Act.

Background:

The Tobacco Control Act was enacted on June 22, 2009, amending the FD&C Act and providing FDA with the authority to regulate tobacco products (Pub. L. 111-31; 123 Stat. 1776). Section 910(a) established requirements for premarket review of new tobacco products. Form FDA 4057b was developed to assist industry and FDA in identifying the products that are the subject of a premarket tobacco product application submission.

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) 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) will be 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 premarket tobacco product applications (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. We expect a number of companies will submit PMTAs on or before this date to receive the benefit of continued marketing.

Need for Emergency Clearance:

If certain conditions are met, an agency head or designee may request expedited OMB review of an information collection request (ICR), also known as an "emergency" review. OMB may grant expedited review if the collection is essential to the mission of the agency, clearance is needed sooner than the normal timeframe, and the agency cannot reasonably comply with the normal clearance procedures of the Paperwork Reduction Act of 1995 (the PRA) because: "(i) public harm is reasonably likely to result if normal clearance procedures are followed; (ii) an unanticipated event has occurred; or (iii) the use of normal clearance procedures is reasonably likely to prevent or disrupt the collection of information or is reasonably likely to cause a statutory or court ordered deadline to be missed" (5 CFR § 1320.13(a)(2)). When OMB expedites review, OMB acts promptly to review the ICR through a suitably streamlined process, consistent with the purposes of the PRA. For example, OMB may modify—or, if necessary,

waive—the public comment requirements. Emergency clearance may be granted for a maximum of six months.

We are seeking emergency processing for the following reasons:

(1) The revision of the collection of information (form FDA 4057b) is needed prior to the expiration of normal clearance time periods and is essential to the mission of the FDA; and

(2) FDA cannot reasonably comply with normal clearance procedures because use of normal clearance procedures is reasonably likely to cause a statutory deadline to be missed and to prevent or disrupt the required collection of information.

The enactment of the Appropriations Act on March 15, 2022, with an effective date of April 14, 2022, does not allow us sufficient time to comply with the normal clearance procedures. The expectation that companies will submit PMTAs on or before May 14, 2022, underscores the need for this revision to be approved expeditiously. This revision will ensure applicants are able to submit, and FDA is able to efficiently process, identifying information about NTN products. Being able to quickly review this identifying information will help FDA determine whether the products that are subject to the application qualify for 60 days of continued marketing.

In addition, without emergency clearance and the accompanying revisions to form FDA 4057b, FDA will be unable to ensure that interested stakeholders will provide complete requests, which include the information necessary to submit premarket tobacco product applications (PMTAs). Furthermore, without the ability to receive information from industry in a standardized format, FDA will be unable to allow for applicants to identify products containing non-tobacco derived nicotine.

FDA is requesting that OMB allow use of its emergency clearance process to immediately approve the revision of OMB Control No. 0910-0879, so that FDA may immediately collect the information necessary to be in alignment with the changes to the definition of "tobacco product" in section 201(rr) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(rr)).

May D. Nelson -S

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