United States Food and Drug Administration

Time and Extent Applications for Nonprescription Drug Products

OMB Control No. 0910-0688 -- REVISION

SUPPORTING STATEMENT

Part A: Justification

1. Circumstances Making the Collection of Information Necessary

This information collection supports certain Food and Drug Administration (FDA, the agency, us or we) regulations in 21 CFR part 330 regarding over-the-counter (OTC) human drugs and associated guidance. Specifically, our regulations in §§ 330.14 and 330.15 (21 CFR 330.14 and 330.15), established additional criteria and procedures for classifying OTC drugs as generally recognized as safe and effective and not misbranded. However, as explained below, these regulations are not reflective of more-recently enacted statutory provisions that govern the regulation of OTC human drugs marketed without approved new drug applications, under the OTC drug review process, and accordingly, these regulations will be withdrawn. These regulations provided that OTC drug products introduced into the U.S. market after the OTC drug review began in 1972 and OTC drug products without any marketing experience in the United States could be evaluated under the OTC monograph system if the conditions (e.g., active ingredients) met certain ‘‘time and extent’’ criteria outlined in the regulations. The regulation in 21 CFR 330.14 allowed a sponsor to submit certain information to the Agency in a time and extent application (TEA) for use to determination the eligibility of a condition for consideration in the OTC monograph system.

We developed the final guidance document entitled, “Time and Extent Applications for Nonprescription Drug Products” (September 2011) (available from our website at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/time-and-extent-applications-nonprescription-drug-products), to assist respondents with the information collection provisions found in the regulations. The guidance was issued consistent with our good guidance practice regulations at 21 CFR 10.115, which provide for comment at any time. The guidance explains what information an applicant should submit to the agency to request that a drug product be included in the OTC drug monograph system. The guidance also discusses format and content elements, and the process for submitting information, consistent with the applicable regulations. Note that when FDA withdraws the TEA regulations, we will discontinue the related guidance document. When these actions occur, we will also request discontinuation of this information collection (presently under OMB control number 0910-0688).

OTC Monograph Reform in the CARES Act

The Coronavirus Aid, Relief, and Economic Security Act (CARES Act (P.L. 116-136, Stat. 281)) signed March 27, 2020, included provisions that govern the way certain OTC drugs are regulated in the United States. The CARES Act added section 505G to the Federal Food, Drug and Cosmetic Act (FD& C Act (21 U.S.C. 355g)) which reforms and modernizes the OTC drug review process, including establishing new procedures for consideration of additions or changes to conditions covered in OTC monographs As a result of these revised statutory provisions, we anticipate no submissions under 21 CFR 330.14. In particular, among other things, the statute now specifies that requestors shall make submissions seeking inclusion of additional conditions in an OTC monograph pursuant to section 505G(5) as an OTC Monograph Order Request (OMOR), along with payment of the appropriate user fee. Under section 505G(o) of the FD&C Act, the Paperwork Reduction Act of 1995 (chapter 35 of title 44, United States Code) does not apply to collections of information made under section 505G of the FD&C Act, which includes OMORs. The information collection associated with the OMOR user fee is approved under OMB Control No. 0910-0340. Our OTC Monographs@FDA portal (https://dps.fda.gov/omuf), provides additional information about OTC monograph drugs and the OTC drug review process.

Consistent with section 505G(k)(3) of the FD&C Act,[1] we plan to withdraw the regulations supporting the TEA provisions in 21 CFR Part 330 and discontinue the related guidance document. When these actions occur, we will also request discontinuation of the information collection approved under OMB Control No. 0910-0688.

We therefore request OMB approval of the information collection provisions found in 21 CFR 330.14, and the final guidance document, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

Under the provisions of 21 CFR 330.14, respondents, any interested party (usually a private sector business), could submit a TEA application to substantiate that an ingredient or ingredients were eligible to be considered for inclusion in the OTC drug monograph system and, if so, to demonstrate that the ingredient or ingredients can be classified as GRASE. We used the information collected to determine eligibility (part of a two-step process) and, if determined eligible, to classify the ingredient(s) as GRASE or not GRASE (second part of the process).

3. Use of Improved Information Technology and Burden Reduction

We do not anticipate further TEA submissions under 21 CFR 330.14.

[1] Section 505G(k)(3) of the FD&C Act provides that regulations establishing final monographs and the procedures governing the OTC drug review under part 330, and other relevant parts of title 21 of the CFR, shall be withdrawn or revised to make technical changes to ensure conformity with appropriate terminology and cross-references. Section 505G(k)(3) of the FD&C Act also provides that any such withdrawal or technical changes shall be made without public notice and comment and shall be effective upon publication through notice in the Federal Register (or upon such date as specified in such notice).

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

There is no undue burden imposed on small entities as a result of the information collection.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory and regulatory requirements.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of August 8, 2023 (88 FR 53497). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

Data will be kept private to the extent allowed by law. In preparing this Supporting Statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

Privacy Act

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted is point of contact name, business telephone number, business email address, and business mailing address. FDA determined that although PII is collected, the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, the contractor or FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate form and webpage design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

Freedom of Information Act

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information, and applicable legal provisions.

As explained previously, due to subsequent statutory revisions, we do not anticipate any further TEA submissions and plan to withdraw the associated regulations.
The TEA regulations provided that certain information submitted in a TEA or a safety and effectiveness submission may be considered confidential. Under 21 CFR 330.14(d), all TEAs are handled as confidential upon receipt until such time as a decision is made on the eligibility of the drug product. If the drug is found to be eligible for inclusion in the OTC drug monograph system, any information that FDA deems confidential under 18 U.S.C. 1905, 5 U.S.C. 552(b), or section 301(j) of the act will be removed from the TEA, and the remainder of the application will be placed on public display in the Division of Dockets Management when the notice of eligibility is published (21 CFR 330.14(d))). If the condition is not found to be eligible, the TEA will not be placed on public display, but a letter from FDA to the applicant stating why the condition was not
found to be eligible will be placed on public display in the Division of Dockets Management (21 CFR 330.14 (d)).

Under 21 CFR 330.14(f), safety and effectiveness data submitted in response to a notice of eligibility will be made publicly available for viewing at the Division of Dockets Management, except data deemed confidential under 18 U.S.C. 1905, 5 U.S.C. 552(b), or section 301(j) of the Federal Food, Drug and Cosmetic Act. Submissions had to clearly identify data considered confidential under these provisions (21 CFR 330.14(f)). Proposed compendial standards were not considered confidential (21 CFR 330.14(f)).

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Estimated Hour Burden:

Table 1.--Estimated Annual Reporting Burden

21 CFR Part; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
330.14 (c) and (d); Time and extent application and submission of information. 330.14 (f) and (i); Submission of safety and effectiveness data, including data and information listed in 330.10(a)(2), a listing of all serious adverse drug experiences that may have occurred (330.14(f)(2)), and an official or proposed compendial monograph (330.14(i)). 330.14(j) and (k); Submitter correspondence with FDA.	1	~1.29	1.29	861.78 hours (861 hours and 47 minutes)	1,112

As a result of the statutory requirements described in Item 1, above, we anticipate no TEA submissions. For purposes of burden calculation, we assume one respondent as a placeholder. Burden we attribute to reporting activities is assumed to be distributed among the individual elements.

The total burden for this information collection is 1,112 hours.

12b. Annualized Cost Burden Estimate

We estimate a total annualized cost of $56,395 per year (using a 2022 wage rate of $65.44/hour (NAICS 325400, 11-3012, Administrative Services Managers) multiplied by the total number of burden hours (861.78 hours)). The total annualized cost burden includes preparation and submission of a TEA with safety and effectiveness data in support of the TEA, and burden related to sponsor correspondence with the FDA.

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

There are no capital or operating and maintenance costs associated with the information collection.

14. Annualized Cost to the Federal Government

We assume, based on estimates for similar information collection activities, that the cost to the Federal government to review one TEA submission is $1,145.78.

15. Explanation for Program Changes or Adjustments

Our estimated burden for the information collection reflects, as a result of statutory requirements, a program change decrease of 6,894 hours and a corresponding decrease of 8 responses.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA will display the OMB expiration date as required by 5 CFR 1320.8.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.