Additional Criteria and Procedures for Classifying Over-the-Counter Drugs as Generally Recognized as Safe and Effective and Not Misbranded

0910-NEW

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

FDA's legal authority to regulate the ingredients contained in over-the-counter (OTC) drug products derives from sections 321, 351, 352, 353, 355, 360, and 371 of the Federal Food, Drug, and Cosmetics Act (the act). FDA follows the procedures outlined in 21 CFR 330.10 for classifying active ingredients in OTC drug products as generally recognized as safe and effective (GRASE) and not misbranded.

A final rule, published on January 23, 2002, specifies additional criteria and procedures by which OTC drugs that were initially marketed in the United States after the OTC drug review began in 1972 and OTC drugs without any U.S. marketing experience may become eligible for consideration in the OTC drug monograph system (67 FR 3060). The regulations, in 21 CFR 330.14[1], define a two-step process to include an ingredient in an OTC drug monograph (i.e., to classify the ingredient as GRASE for a particular purpose). First, to determine whether a drug product is eligible to be considered for inclusion in the OTC drug monograph system, certain information must be submitted to FDA in a time and extent application (TEA) to show that a drug product meets the criteria described in 21 CFR 330.14(b) (see 21 CFR 330.14(c) and (d)). Second, if the drug product is found eligible, FDA will publish a notice of eligibility in the *Federal Register* that requests that interested persons submit data to demonstrate the safety and effectiveness of the drug product for its OTC use(s) (21 CFR 330.14(f)).

This collection of information is not related to the American Recovery and Reinvestment Act of 2009.

2. Purpose and Use of the Information Collection

Interested parties (private sector businesses) collect information under the provisions of 21 CFR 330.14 to substantiate that an ingredient or ingredients are 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.

[1] Attachment 1

FDA uses the information collected to determine eligibility (first part of 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

FDA expects information to be collected, reviewed, compiled, and submitted electronically where possible. Based on our experience to date, FDA estimates that 95 percent or more of the responses will be submitted electronically. FDA no longer requires that collected information be submitted in hard copy and would prefer that the information be submitted electronically. Submissions received in the last several years have been exclusively (100 percent) in electronic format.

4. Efforts to Identify Duplication and Use of Similar Information

The data and information collected under the provisions of 21 CFR 330.14 do not duplicate any other data and information that may be available to FDA. No other FDA regulations require submission of the information required by 21 CFR 330.14(c) and (d). FDA may have data required by 21 CFR 330.14(f) and (i) if it was submitted under new drug applications (NDAs). In such situations, the data from NDAs can be cross-referenced to support the requirements of 21 CFR 330.14(f) and (i) and need not be resubmitted.

5. Impact on Small Businesses or Other Small Entities

There are no exceptions for small businesses/marketing enterprises.

6. Consequences of Collecting the Information Less Frequently

The collections of information required under the provisions of 21 CFR 330.14 are one-time burdens for the submitting parties. This information is needed to determine whether the requirements of 21 USC 321(p) are satisfied.

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

A 60-day notice was published in the *Federal Register* on October 8, 2010 (75 FR 62404)[2]. We received one comment (FDA-2010-N-0493-0002) and have modified our estimates of burden based on that comment. There have been no consultations with other government agencies.

9. Explanation of Any Payment or Gift to Respondents

This section is not applicable.

10. Assurance of Confidentiality Provided to Respondents

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 act. Submissions must clearly identify data considered confidential under these provisions (21 CFR 330.14(f)). Proposed compendial standards will not be considered confidential (21 CFR 330.14(f)).

11. Justification for Sensitive Questions

This section is not applicable

[2] Attachment 2

12. Estimates of Annualized Burden Hours and Costs

a. Estimated Annual Burden Hours

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
330.14(c) and (d)[1]	2	1	2	1,525	3,050
330.14(f) and (i)[2]	2	1	2	2,350	4,700
Total					7,750

b. Annualized Cost Burden Estimate

Using a 2009 wage estimate of $49.47 per hour[3], preparation of two TEAs per year will result in costs of approximately $151,000 per year ($49.47 per hour times 3,050 hours). Preparation of information to support the safety and effectiveness of TEA ingredients will cost approximately $232,500 per year (($49.47 per hour times 4,700 hours). Total annualized cost burden is estimated to be approximately $383,500 per year ($151,000 plus $232,500).

No. of Respondents	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
2	7,750	$49.47	$383,500

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no capital, start-up, operating, or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

We do not anticipate that any costs associated with meeting the requirements of 21 CFR 330.14 will be borne by the federal government.

15. Explanation for Program Changes or Adjustments

[3] Wage estimate provided by L'Oreal in document number FDA-2010-N-0493-0002.

This section is not applicable.

16. Plans for Tabulation and Publication and Project Time Schedule

This section is not applicable.

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

This section is not applicable.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.