

## **A. Justification**

### **1. Circumstances Which Make This Information Collection**

Section 409(a) of the Federal Food, Drug and Cosmetic Act (FFDCA) provides that a food additive shall be deemed to be unsafe unless its use is permitted by a regulation which prescribes the condition(s) under which it may safely be used, or unless it is exempted by regulation for investigational use. Section 409(b) of FFDCA specifies the information that must be submitted by a petition in order to establish the safety of a food additive and to secure the issuance of a regulation permitting its use.

To implement the provision of Section 409, procedural regulations have been issued under Part 571 of 21 CFR. These procedural regulations are designed to specify more thoroughly the information that must be submitted to meet the requirement set down in broader terms by the law. The regulations add no substantive requirements to those indicated in the law, but attempt to explain the requirements and provide a standard format for submission to speed the processing of the petition. Labeling requirements for food additives intended for animal consumption are also set forth in various regulations contained in Parts 572, 573, and 580. The labeling regulations are considered by FDA to be cross referenced to 571.1, which is the subject of this same OMB clearance for food additive petitions.

We are requesting OMB approval of the following information collection requirements under 21 CFR Part 571:

21 CFR 571.1 ( c ) *complex category* - Reporting - Specifies format and data to be submitted in filing food additive petition with complex chemistry, manufacturing, efficacy and or safety issues.

21 CFR 571.1 ( c ) *moderate category* - Reporting - Specifies format and data to be submitted in filing a food additive petition without complex chemistry, manufacturing, efficacy or safety issues.

21 CFR 571.6 - Reporting - Submission of additional information or data ( amendment) in support of a food additive petition.

### **2. How, by Whom and the Purpose for Collecting This Information**

Food additive petitions, submitted by food manufacturers or food additive manufacturers, are reviewed by FDA scientific personnel to ascertain if the data establish the identity of the substance, justify its

intended effect in/on the food, and establish that its intended use in/on food is safe. The petitions themselves may contain privileged information that will not be made public and will not be directly published. However, favorable action on the petition requires publication of a regulation in the Federal Register establishing the conditions under which the additive may be safely used in food.

The labeling information for food, such as proper name of the product, the name and address of the manufacturer of the product, and other requirements such as net weight statements, are specifically required by FFDCA and other Acts enforced by FDA.

Food additive petitions provide the only method to bring new food additives to market.

### **3. Use of Technology to Reduce the Burden on the Public**

In a **Federal Register** final rule of March 20, 1997 (62 FR 13464), FDA published 21 CFR Part 11, Electronic records; electronic signatures. These regulations apply to all FDA program areas and to any paper records required by statute or agency regulations. On January 28, 1999 (64 FR 4433), FDA announced the availability of guidance for industry on Providing Regulatory Submission in Electronic Format - General Considerations. CVM participated in a number of the discussions and meetings with CDER, CBER and other centers on agency standards for electronic submissions. These discussions were designed to ensure that agency-wide requirements are generally suitable for all electronic submissions to the agency. CVM expects the guidance would be also suitable for food additive petitions under 21 CFR 571.1. Parts 573 do not prohibit the use of improved technology that may be appropriate to satisfy the labeling requirements for food additives

### **4. Identification and Use of Duplicate Information**

There are no other regulations or Federal Agencies that require the submission of the same type information. There is no similar data/information that could be substituted for that required by these regulations.

FDA continues to work with EPA and USDA to eliminate areas of duplicate data collection and evaluation. There is no duplication of FDA labeling requirements by other U.S. government agencies.

Memoranda of understanding have been reached with EPA in the areas of pesticides and water treatment. EPA establishes a tolerance, or exemption from tolerance, for pesticide chemicals and residues of such chemicals in food, and FDA enforces the tolerance or exemption.

### **5. FDA's Efforts to Reduce Burden on Small Business**

There is no impact on small business or other small entities.

## **6. Impact of Not Collecting This Information or Collecting Information Less Frequently**

Companies have a right, granted by law, to submit food additive petitions in order to market a new food additive or to expand the use of a currently regulated food additive. Restriction of this right would lower the number of food additives being cleared for use would have no detrimental effects on Federal activities.

The consequence of discontinuing labeling requirements would be the possible misuse of food additives, resulting in the introduction of unsafe food into interstate commerce. Each container of a food additive must be properly labeled to assure safe use of the additive and to safeguard the public health. Additionally, food must be identified on the label of retail packages of foods.

Section 409(a) of the Federal Food, Drug and Cosmetic Act specifies that a food additive is unsafe unless it conforms to a regulation prescribing the conditions under which it may safely be used, or unless it is exempted by regulation for investigational use. Section 409(b) of FFDCA specifies the information that must be submitted by a petitioner in order to establish the safety of a food additive and to secure the issuance of a regulation permitting its use. 21 CFR Part 571 provides a standard format for food additive petitions in order to facilitate the processing of the petition and hence the issuance of a regulation as required by FFDCA.

## **7. Special Circumstances That Occur When Collecting This Information**

There are no special circumstances for the collection of the information requirements.

## **8. Identification of Outside FDA Sources**

In accordance with 5 CFR 1320.8(d), on November 12, 2003 (68 FR 64110), a 60-day notice for public comment was published in the **Federal Register**. No comments were received from the public in response to that notice.

## **9. Payment or Gifts Offered to Respondents**

No payment or gift is provided to respondents.

## **10. Method of Ensuring Respondent Confidentiality**

Because food additive petitions often contain trade secret information, all files are maintained in a secured area. Confidentiality of data and information in food additive petitions is regulated under 21 CFR 571.1. The information is also safeguarded by Section 301 (j) of the Federal Food Drug and Cosmetic Act, (FFDCA).

## 11. Use of Sensitive Questions

This information does not contain questions pertaining to sex behavior, attitude, religious beliefs, or any other matter commonly considered private or of a sensitive nature. There are no questions of a sensitive nature in the food additive petition requirements.

## 12. Burden Hours and Cost Associated With This Information Collection

The estimated annual burden for this information collection is 13,000 hours.

Food additive petitions submitted to CVM are estimated to fall into one of two categories of complexity that also can be used to represent estimates of the information collection burden for food additive petitions. These include only expected petitions for food additives not eligible for exemption under new Section 409(h) of FFDCFA.

*571.1(c) moderate category:* For food additive petition without complex chemistry, manufacturing, efficacy or safety issues, the estimated time requirement per petition is approximately 3,000 hours. An average of 1 (one) petitions of this type is received on an annual basis, resulting in a burden of 3,000 hours.

*571.1(c) complex category:* For a food additive petition with complex chemistry, manufacturing, efficacy and/or safety issues, the estimated time requirement per petition is approximately 10,000 hours. An average of 1 (one) petition of this type is received on an annual basis, resulting in a burden of 10,000 hours.

*571.6:* For a food additive petition amendment, the estimated time requirement per petition is approximately 1,300 hours. An average of 4 (four) petitions of this type is received on an annual basis, resulting in a burden of 5,200 hours.

Thus, FDA estimates the burden for this collection of information as follows:

Estimated Annual Reporting Burden <sup>1</sup>					
Category	No. of Respondents	Annual Frequency of Response	Total Annual Responses	Hours per Response	Total Hours
571.1(c) moderate category	1	1	1	1800	1800
571.1(c) complex category	1	1	1	6000	6000
571.6	2	2	4	1300	5200
Total Hours					13,000

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

### **13. Annual Cost Estimate to Respondents**

There are no additional annual costs to respondents.

### **14. Annual Cost Estimate to FDA**

For fiscal year 2002, the Food and Drug Administration reports 1 person-years of professional time in the review of food additive petitions in CVM. Based on an average cost of \$110,000 per fully supported position, the cost of processing food additive petitions in fiscal year 2002 was \$67,283.00 in CVM. The annualized cost to the federal government of processing petitions is derived by multiplying the person-years used in processing petitions by the dollar value per supported position.

We anticipate that the review of a food additive petition will require the services of a GS-14 review scientist for 1000 hours at an hourly rate of \$33.64 per hour. The cost for the one-time review would be 33,640.00.

Thus, the total average cost to CVM of reviewing and approving food additive petitions is \$67,283.00, which is equal to the total average number of hours required (2,000 times a wage rate of \$33.64 per hour)

### **15. Changes from Previous Approval**

N / A

### **16. Publishing the Results of This Information Collection**

There are no results to publish for this information collection. Food additive petitions are submitted for regulatory purposes and the data in these petitions are not intended for statistical use. Notification is published in the Federal Register when a food additive petition is filed (in accordance with 21 CFR 57.1.1) and when a regulation has been promulgated (in accordance with 21 CFR 571.100).

### **17. Reason for Not Displaying the OMB Approval Date**

FDA is not seeking approval to exempt display of the expiration date for OMB approval.

### **18. Explanations to Section 19, Certification for Paperwork Reduction Act Submissions**

There are no exceptions to Item 19 of OMB Form 83-I.