alternative ways. A biowaiver may be granted if it can be shown that the generic soluble powder oral dosage form product or Type A medicated article contains the same active and inactive ingredient(s) and is using the same manufacturing processes as the approved comparator product or article. Alternatively, a biowaiver may be granted without direct comparison to the pioneer product's formulation and manufacturing process if it can be shown that the active pharmaceutical ingredient(s), is the same as the pioneer product, is soluble , and that there are no ingredients in the formulation likely to cause adverse pharmacologic effects. For the purpose of evaluating soluble powder oral dosage form products and Type A medicated articles, solubility can be demonstrated in two ways: ''USP definition'' approach or ''Dosage Adjusted'' approach.

In the **Federal Register** of August 3, 2004 (69 FR 46553), the agency requested comments on this collection of information. In response to that notice, the agency received several comments on the guidance, two from individuals who were generally favorable and one from the Animal Health Institute (AHI), which was supportive of some aspects of the proposed guidance and not supportive of others. None of the comments received took issue with any aspect of the paperwork burden associated with the draft policy. The Center for Veterinary Medicine has revised the substance of the proposed guidance in several respects in response to AHI comments.

The respondents for this collection of information are pharmaceutical companies manufacturing animal drugs. FDA estimates the burden for this collection of information as follows in tables 1 and 2 of this document. The source of the data is records of generic drug applications over the past 10 years.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN FOR WATER SOLUBLE POWDERS[1]

	No. of Respondents	Annual Frequency per Responses	Total Annual Responses	Hours per Response	Total Hours
Same Formulation / Manufacturing Process Approach	1	1	1	5	5
Same API / Solubility Approach	5	5	5	10	50
Total Burden Hours					55

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN FOR TYPE A MEDICATED ARTICLES[1]

	No. of Respondents	Annual Frequency per Responses	Total Annual Responses	Hourse per Response	Total Hours
Same Formulation / Manufacturing Process Approach.	2	2	2	5	10
Same API / Solubility Approach	10	10	10	20	200
Total Burden Hours					210

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: October 17, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–21154 Filed 10–21–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0209]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Food Contact Substances Notification

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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: Fax written comments on the collection of information by November 23, 2005.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA 250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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.

Food Contact Substances Notification System—21 CFR 170.101 and 170.106—(OMB Control Number 0910–0495)—Extension

Section 409(h) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(h)) establishes a premarket notification process for food contact substances. Section 409(h)(6) of the act defines a ''food contact substance'' as ''any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.'' Section 409(h)(3) of the act requires that the notification process be used for authorizing the marketing of food contact substances

except where FDA determines that the submission and premarket review of a food additive petition (FAP) under section 409(b) of the act is necessary to provide adequate assurance of safety or where FDA and the manufacturer or supplier agree that an FAP should be submitted. Section 409(h)(1) of the act requires that a notification include information on the identity and the intended use of the food contact substance and the basis for the manufacturer's or supplier's determination that the food contact substance is safe under the intended conditions of use.

Sections 170.101 and 170.106 of FDA's regulations (21 CFR 170.101 and 170.106) require that a food contact notification (FCN) include FDA Form 3480 entitled ''Notification for New Use of a Food Contact Substance'' and that a notification for a food contact substance formulation include FDA Form 3479 entitled ''Notification for a Food Contact Substance Formulation.'' These forms will serve to summarize pertinent information in the notification. FDA believes that these forms will facilitate both preparation and review of notifications because the forms will serve to organize information necessary to support the safety of the use of the food contact substance. The burden of filling out the appropriate form has been included in the burden estimate for the notification.

Description of Respondents: Manufacturers of food contact substances.

In the **Federal Register** of June 7, 2005 (70 FR 33180), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Form	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
170.106[2] (Category A)	5	FDA 3479	1	5	2	10
170.101[3,7] (Category B)	5	FDA 3480	1	5	25	125
170.101[4,7] (Category C)	5	FDA 3480	2	10	120	1,200
170.101[5,7] (Category D)	33	FDA 3480	2	66	150	9,900
170.101[6,7] (Category E)	30	FDA 3480	1	30	150	4,500
Total						15,735

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Notifications for food contact substance formulations and food contact articles. These notifications require the submission of FDA form 3479 (''Notification for a Food Contact Substance Formulation'') only.
[3] Duplicate notifications for uses of food contact substances.
[4] Notifications for uses that are the subject of exemptions under 21 CFR 170.39 and very simple food additive petitions.
[5] Notifications for uses that are the subject of moderately complex food additive petitions.
[6] Notifications for uses that are the subject of very complex food additive petitions.
[7] These notifications require the submission of FDA Form 3480.

These estimates are based on FDA's experience with the food contact substances notification system.

- Based on input from industry sources, FDA estimates that the agency will receive approximately five notifications annually for food contact substance formulations.
- FDA also has included five expected duplicate submissions in the second row of table 1 of this document. FDA expects that the burden for preparing these notifications primarily will consist of the manufacturer or supplier filling out FDA Form 3480, verifying that a previous notification is effective, and preparing necessary documentation.
- Based on the submissions received, FDA identified three other tiers of FCNs that represent escalating levels of burden required to collect information (the third, fourth and fifth rows of table 1 of this document).
- FDA estimated the median number of hours necessary for collecting information for each type of notification within each of the three tiers based on input from industry sources.

Dated: October 17, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–21155 Filed 10–21–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0396]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Formal Dispute Resolution; Appeals Above the Division Level

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to