TABLE 2.—ESTIMATED RECORDKEEPING ANNUAL BURDEN[1]—Continued

	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
Total					660

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

The annual burden estimate for this information collection is 3,204 hours. The estimated reporting burden for this collection is 2,544 hours, and the estimated recordkeeping burden is 660 hours.

In the **Federal Register** of April 20, 2009 (74 FR 17962), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received. However, in the period of time since the 60-day notice was drafted, there was a determination of public health emergency involving the 2009 H1N1 virus and multiple declarations supporting the issuance of EUAs. As a result of this increased activity and the likelihood of a continued increase in the number of EUA and pre-EUA submissions, on its own initiative, FDA is providing estimates based on the number of reports that the agency received in the past year.

Dated: September 29, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–24048 Filed 10–5–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0465]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food Additive Petitions

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 publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on food additive petitions regarding animal feed.

DATES: Submit written or electronic comments on the collection of information by December 7, 2009.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley Jr., Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3793.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Food Additive Petitions—21 CFR Part 571 (OMB Control Number 0910–0546)—Extension

Section 409(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(a)) 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 the act 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 of the act, procedural regulations have been issued under part 571 (21 CFR part 571). 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 seek to explain the requirements and provide a standard format for submission of petitions, that when implemented, will speed up the time for processing. Labeling requirements for food additives intended for animal consumption are also set forth in various regulations contained in 21 CFR parts 573, 582, and 584. 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.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
571.1(c) moderate category	1	1	1	3,000	3,000
571.1(c) complex category	1	1	1	10,000	10,000
571.6 amendment of petition	2	2	4	1,300	5,200
Total Hours					18,200

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

FDA derived the annual reporting burden estimate for the different categories as follows:

Section 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.

Section 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.

Section 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, the estimated total annual burden for this information collection is 18,200 hours.

Dated: September 29, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–24047 Filed 10–05–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Establishment

Pursuant to the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), the Director, National Institutes of Health (NIH), announces the establishment of the Interagency Breast Cancer and Environmental Research Coordinating Committee (Committee).

The Committee shall coordinate all efforts within the Department of Health and Human Services to share and coordinate information on existing research activities, and make recommendations to the Secretary DHHS, the National Institutes of Health and other Federal agencies regarding how to improve existing research programs.

The Committee's primary mission is to facilitate the efficient and effective exchange of information on breast cancer research activities among the member agencies, and to coordinate solicitation of proposals for collaborative, multidisciplinary research, including proposals to evaluate environmental and genomic factors that may be related to the etiology of breast cancer.

Duration of this committee is two years from the date the Charter is filed.

Francis S. Collins,

Director, National Institutes of Health.

[FR Doc. E9–23974 Filed 10–5–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2009–M–0033, FDA–2009–M–0016, FDA–2009–M–0034, FDA–2009–M–0049, FDA–2009–M–0071, FDA–2009–M–0127, FDA–2009–M–0128, FDA–2009–M–0135, FDA–2009–M–0159]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the agency's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness data to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Nicole Wolanski, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1650, Silver Spring, MD 20993, 301–796–6570.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the **Federal Register**. Instead, the agency now posts this information on the Internet on FDA's home page at *http://www.fda.gov*. FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the