demographic questions will be included. The form will ask participants to report demographic information, education, profession, field of study, status of certification or licensure, workplace role, and employment setting.

Follow-up Form for Training: The Follow-up Information Form for Training asks about 25 questions of about 25% of consenting participants. The approved form asks the participants to report satisfaction with, usefulness of, and quality of the training and training materials as well as to assess their level of skills in the topic area. The form also asks participants to report whether or not they have shared information from the event at their place of work and which, if any, barriers they have encountered to applying the information gained from the training. This form is already approved by OMB and will not be revised (OMB #0930–0216).

The information collected on the ATTC forms will assist CSAT in documenting the numbers and types of participants in ATTC events, describing the extent to which participants report improvement in their clinical competency, and which method is most effective in disseminating knowledge to various audiences. This type of information is crucial to support CSAT in complying with GPRA reporting requirements and will inform future development of knowledge dissemination activities.

The chart below summarizes the annualized burden for this project.

Type of respondent	Number of respondents	Responses per respondent	Hours per response	Total annual burden hours
Faculty/staff Event Description Form	250	1	.25	62.50
Meeting and Technical Assistance Participants:				
Post-Event Form	5,000	1	.12	600
Follow-up Form	Covered under CSAT Government Performance and Results Act (GPRA) Customer Satisfaction form (OMB #0930–0197)			
Training Participants:				
Post-Event Form	30,000	1	.16	4,800
Follow-up Form	7,500	1	.16	1,200
Total	42,750			6,662.50

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 7–1044, One Choke Cherry Road, Rockville, MD 20857 *and* e-mail her a copy at *summer.king@samhsa.hhs.gov*. Written comments should be received within 60 days of this notice.

Dated: September 28, 2009.

Elaine Parry,

Director, Office of Program Services.

[FR Doc. E9–24017 Filed 10–5–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0163]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance, Emergency Use Authorization of Medical Products

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 5, 2009.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB Control Number 0910–0595. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794, *JonnaLynn.Capezzuto@fda.hhs.gov*.

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.

Draft Guidance, Emergency Use Authorization of Medical Products—(OMB Control Number 0910–0595)—Extension

The draft guidance describes the agency's general recommendations and procedures for issuance of emergency use authorizations (EUA) under section 564 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360bbb–3), which was amended by the Project BioShield Act of 2004 (Pub. L. 108–276). The act permits the FDA Commissioner (the Commissioner) to authorize the use of unapproved medical products or unapproved uses of approved medical products during an emergency declared under section 564 of the act. The data to support issuance of an EUA must demonstrate that, based on the totality of the scientific evidence available to the Commissioner, including data from adequate and well-controlled clinical trials (if available), it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing a serious or life-threatening disease or condition (21 U.S.C. 360bbb–3(c)). Although the exact type and amount of data needed to support an EUA may vary depending on the nature of the declared emergency and the nature of the candidate product, FDA recommends that a request for consideration for an EUA include scientific evidence evaluating the product's safety and effectiveness, including the adverse event profile for diagnosis, treatment, or prevention of the serious or life-threatening disease or condition, as well as data and other information on safety, effectiveness, risks and benefits, and (to the extent available) alternatives.

Under section 564 of the act, the FDA Commissioner may establish conditions on the approval of an EUA. Section 564(e) requires the FDA Commissioner (to the extent practicable given the

circumstances of the emergency) to establish certain conditions on an authorization that the Commissioner finds necessary or appropriate to protect the public health and permits the FDA Commissioner to establish other conditions that he finds necessary or appropriate to protect the public health. Conditions authorized by section 564(e) of the act include, for example: Requirements for information dissemination to health care providers or authorized dispensers and product recipients; adverse event monitoring and reporting; data collection and analysis; recordkeeping and records access; restrictions on product advertising, distribution, and administration; and limitations on good manufacturing practices requirements. Some conditions, the statute specifies, are mandatory to the extent practicable for authorizations of unapproved products and discretionary for authorizations of unapproved uses of approved products. Moreover, some conditions may apply to manufacturers of an EUA product, while other conditions may apply to any person who carries out any activity for which the authorization is issued. Section 564 of the act also gives the FDA Commissioner authority to establish other conditions on an authorization that he finds to be necessary or appropriate to protect the public health.

For purposes of estimating the burden of reporting, FDA has established six categories of respondents: (1) Those who file a Request for Consideration for an EUA and, in lieu of submitting the data, provide reference to a pending or approved application; (2) those who file a Request for Consideration for an EUA, without reference to a pending or approved application; (3) those who submit pre-EUA submissions to FDA on a candidate EUA product, which references a pending or approved application; (4) those who submit pre-EUA submissions to FDA on a candidate EUA product, for which there is no reference to a pending or approved application; (5) manufacturers of an unapproved EUA product who must report to FDA regarding such activity; and (6) state and local public health officials who carry out an activity related to an unapproved EUA product (e.g., administering the product to recipients) and who must report to FDA regarding such activity.

For purposes of estimating the burden of recordkeeping, FDA has calculated the anticipated burden on manufacturers of unapproved products authorized for emergency use. FDA also anticipates that some state and local public health officials may be required to perform additional recordkeeping (e.g., related to the administration of unapproved EUA products to civilians) and calculated a recordkeeping burden for those activities.

No burden was attributed to reporting or recordkeeping for unapproved uses of approved products, since those products already are subject to approved collections of information (adverse experience reporting for biological products is approved under OMB Control No. 0910–0308 through September 30, 2011; adverse drug experience reporting is approved under OMB Control No. 0910–0230 through July 31, 2012; investigational new drug application regulations are approved under OMB Control No. 0910–0014 through August 31, 2011; and investigational device exemption reporting is approved under OMB Control Number 0910–0078 through January 31, 2010). Thus, FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Requests for Consideration; Pending Application on File	5	2	10	15	150
Requests for Consideration; No Application Pending	4	2	8	50	400
Pre-EUA Submissions; Pending Application on File	2	2	4	20	80
Pre-EUA Submissions; No Application Pending	11	2	22	75	1,650
Manufacturers of an Unapproved EUA Product	3	4	12	2	24
State and Local Public Health Officials; Unapproved EUA Product	30	4	360	2	240
Total					2,544

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

TABLE 2.—ESTIMATED RECORDKEEPING ANNUAL BURDEN[1]

	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
Manufacturers of an Unapproved EUA Product	3	4	12	25	300
State and Local Public Health Officials; Unapproved EUA Product	30	4	120	3	360

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]

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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: