



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0976]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; 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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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: 202-395-7285, or emailed to oir_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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRASStaff@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.

Emergency Use Authorization of Medical Products and Related Authorities; Guidance for
Industry and Public Health Stakeholders

OMB Control Number 0910-0595--Extension

The 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 FD&C Act) (21 U.S.C. 360bbb-3), which was amended by the Project BioShield Act of 2004 (Pub. L. 108-276). The FD&C Act permits 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 FD&C 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 FD&C Act, the FDA Commissioner may establish conditions on the authorization. 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 she finds necessary or appropriate to protect the public health. Conditions authorized by section 564(e) of the FD&C 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 FD&C Act also gives the FDA Commissioner authority to establish other conditions on an authorization that she finds to be necessary or appropriate to protect the public health.

For purposes of estimating the annual burden of reporting (table 1), FDA has established four categories of respondents: (1) Those who file a request for FDA to issue an EUA or a substantive amendment to an EUA that has previously been issued, assuming that a requisite declaration under section 564 of the FD&C Act has been made and criteria for issuance have been met; (2) those who submit a request for FDA to review information/data (i.e., a pre-EUA package) for a candidate EUA product or a substantive amendment to an existing pre-EUA package for preparedness purposes; (3) manufacturers who carry out an activity related to an unapproved EUA product (e.g., administering product, disseminating information) who must

report to FDA regarding such activity; and (4) public health authorities (e.g., State, local) who carry out an activity (e.g, administering product, disseminating information) related to an unapproved EUA product who must report to FDA regarding such activity.

In some cases, manufacturers directly submit EUA requests. Often a Federal Government entity (e.g., the Centers for Disease Control and Prevention, Department of Defense) requests that FDA issue an EUA and submits pre-EUA packages for FDA to review. In many of these cases, manufacturer respondents inform these requests and submissions, which are the activities that form the basis of the estimated reporting burdens. However, in some cases the Federal Government is the sole respondent; manufacturers do not inform these requests or submissions. FDA estimates minimal burden when the Federal Government performs the relevant activities. In addition to variability based on whether there is an active manufacturer respondent, other factors also inject significant variability in estimates for annual reporting burdens. A second factor is the type of product. For example, FDA estimates greater burden for novel therapeutics than for certain unapproved uses of approved products. A third significant factor that injects variability is the type of submission. For example, FDA estimates greater burden for "original" EUA and pre-EUA submissions than for amendments to them, and FDA estimates minimal burden to issue an EUA when there is a previously reviewed pre-EUA package or investigational application. For purposes of estimating the reporting burden, FDA has calculated the anticipated burden on manufacturers based on the anticipated types of responses (i.e., estimated manufacturer input), types of product, and types of submission that comprise the described reporting activities.

For purposes of estimating the annual burden of recordkeeping, FDA has also calculated the anticipated burden on manufacturers and public health officials associated with

administration of unapproved products authorized for emergency use, recognizing that the Federal Government will perform much of the recordkeeping related to administration of such products (table 2).

No burden was attributed to reporting or recordkeeping for unapproved uses of approved products, since those products are already subject to approved collections of information (i.e., adverse experience reporting for biological products is approved under OMB control number 0910-0308 through February 28, 2018; adverse drug experience reporting is approved under OMB control number 0910-0230 through December 31, 2018; adverse device experience reporting is approved under OMB control number 0910-0471 through May 31, 2017; investigational new drug application regulations are approved under OMB control number 0910-0014 through February 28, 2019; and investigational device exemption reporting is approved under OMB control number 0910-0078 through March 31, 2016). Any additional burden imposed by this proposed collection would be minimal.

In the Federal Register of December 23, 2015 (80 FR 79905), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

Table 1.--Estimated Annual Reporting Burden¹

Type of Respondent	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Manufacturer, Request to Issue an EUA or a Substantive Amendment to an Existing EUA	6	3	18	45	810
Manufacturer, Request for FDA Review of a Pre-EUA Package or an Amendment Thereto	13	6	78	34	2,652

Manufacturer of an Unapproved EUA Product; Conditions of Authorization	5	2	10	2	20
Public Health Authority; Unapproved EUA Product; Conditions of Authorization	30	3	90	2	180
Total					3,662

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

Table 2.--Estimated Annual Recordkeeping Burden¹

Type of Respondent	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Manufacturers of an Unapproved EUA Product	5	2	10	25	250
Public Health Authorities; Unapproved EUA Product	30	3	90	3	270
Total					520

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

Dated: March 7, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-05390 Filed: 3/9/2016 8:45 am; Publication Date: 3/10/2016]