CY 2011 ANNUAL REPORTING BURDEN—Continued

| Data collection activity | Number of respondents | Responses per respondent | Total responses | Average hours per response | Total hour burden |
|---|---|---|---|---|---|
| 12 months | 879 | 1 | 879 | 0.92 | 809 |
| Sub Total | 3,957 | | 3,957 | | 3,487 |
| **Record Management by FY2008 and anticipated FY2009 and FY2010 Grantee Staff** | | | | | |
| Events Tracking | 18 | 800 | 14,400 | 0.03 | 432 |
| Person Tracking | 18 | 80 | 1,440 | 0.1 | 94 |
| Service Use | 18 | 50 | 900 | 0.17 | 153 |
| Arrest History | 18 | 50 | 900 | 0.17 | 153 |
| Sub Total | 72 | | 17,640 | | 832 |
| **FY2008 and FY2009 Grantees** | | | | | |
| Interview and Tracking data submission | 18 | 12 | 48 | 0.17 | 8 |
| Overall Total | 4047 | | 21,645 | | 4,327 |

CY 2012 ANNUAL REPORTING BURDEN

| Data collection activity | Number of respondents | Responses per respondent | Total responses | Average hours per response | Total hour burden |
|---|---|---|---|---|---|
| **Client Interviews for anticipated FY2009 and 2010: Revised Instrument** | | | | | |
| Baseline (at enrollment) | 1,200 | 1 | 1,200 | 0.83 | 996 |
| 6 months | 1,080 | 1 | 1,080 | 0.92 | 994 |
| 12 months | 1,084 | 1 | 1,084 | 0.92 | 998 |
| Sub Total | 3,364 | | 3,364 | | 2,987 |
| **Record Management by anticipated FY2009 and FY2010 Grantee Staff** | | | | | |
| Events Tracking | 12 | 800 | 9,600 | 0.03 | 288 |
| Person Tracking | 12 | 70 | 840 | 0.1 | 55 |
| Service Use | 12 | 25 | 300 | 0.17 | 51 |
| Arrest History | 12 | 25 | 300 | 0.17 | 51 |
| Sub Total | 48 | | 11,040 | | 445 |
| **FY2008 and FY2009 Grantees** | | | | | |
| Interview and Tracking data submission | 18 | 12 | 48 | 0.17 | 8 |
| Overall Total | 3,424 | | 14,452 | | 3,440 |

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: April 13, 2009.

**Elaine Parry,**

*Director, Office of Program Services.*

[FR Doc. E9–8984 Filed 4–17–09; 8:45 am]

**BILLING CODE 4162–20–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2009–N–0163]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Draft Guidance, Emergency Use Authorization of Medical Products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 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 the proposed extension of the collection of information related to emergency use authorizations (EUAs) by the agency.

**DATES:** Submit written or electronic comments on the collection of information by June 19, 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:** Jonna Capezzuto, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794.

**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.

**Reporting and Recordkeeping for 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 EUAs 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 (Public Law 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 Commissioner may establish conditions on the approval of an EUA. Section 564(e) of the act requires the 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 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: (1) Requirements for information dissemination to health care providers or authorized dispensers and product recipients; (2) adverse event monitoring and reporting; (3) data collection and analysis; (4) recordkeeping and records access; (5) restrictions on product advertising, distribution, and administration; and (6) 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 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 after a determination of actual or potential emergency 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 and the data after a determination of actual or potential emergency, without reference to a pending or approved application; (3) those who submit data to FDA on a candidate EUA product, which is subject to a pending or approved application, prior to a determination of actual or potential emergency; (4) those who submit data to FDA prior to a determination of actual or potential emergency about a candidate EUA product for which there is no 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 civilians) 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. The Agency anticipates that the federal government will perform some of the additional recordkeeping necessary for unapproved products (e.g., related to the administration of unapproved EUA products to military personnel). 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 April 30, 2009; and IND regulations are approved under OMB Control No. 0910–0014 through May 31, 2009) and any additional burden imposed by this proposed collection would be minimal. 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 |
|---|---|---|---|---|---|
| Request for Consideration; Pending Application on File | 1 | 1 | 1 | 15 | 15 |
| Request for Consideration; No Application Pending | 1 | 1 | 1 | 50 | 50 |
| Pre-Emergency Submissions; Pending Application on File | 10 | 1 | 10 | 20 | 200 |
| Pre-Emergency Submissions; No Application Pending | 3 | 1 | 3 | 75 | 225 |
| Manufacturers of an Unapproved EUA Product | 3 | 4 | 12 | 2 | 24 |
| State and Local Public Health Officials; Unapproved EUA Product | 30 | 4 | 120 | 2 | 240 |
| Total | | | | | 754 |

[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 |
| 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 1,414 hours. The estimated reporting burden for this collection is 754 hours and the estimated recordkeeping burden is 660 hours.

Dated: April 10, 2009.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E9–8922 Filed 4–17–09; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

### Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

**Project: Evaluation of Networking Suicide Prevention Hotlines (OMB No. 0930–0274)—Revision**

This project revision includes the continuation of two previously approved data collection activities [Evaluation of Networking Suicide Prevention Hotlines Follow-Up Assessment (OMB No. 0930–0274) and Call Monitoring of National Suicide Prevention Lifeline Form (OMB No. 0930–0275)], and a revision to expand the scope of the ongoing evaluation in an effort to advance the understanding of crisis hotline utilization and its impact. The Substance Abuse and Mental Health Services Administration's (SAMHSA), Center for Mental Health Services (CMHS) funds a National Suicide Prevention Lifeline Network (NSPL), consisting of two toll-free telephone numbers, that route calls from anywhere in the United States to a network of local crisis centers. In turn, the local centers link callers to local emergency, mental health, and social service resources.

The overarching purpose of the proposed Evaluation of the Networking Suicide Prevention Hotlines—Revision is to (1) continue to monitor and ensure quality of calls and gather follow-up information from the callers themselves, (2) expand the number of centers participating in order to assess whether the two national suicide prevention hotline numbers (*i.e.,* 1–800–273–TALK and 1–800–SUICIDE) reach similar or complimentary populations of at risk callers, and, (3) to evaluate additional but related activities (*e.g.,* motivational interviewing and safety planning) recently funded through a new cooperative agreement between