

information provided in each table, chart, attachment, etc., is consistent with the proposal narrative and information in other tables.

Be organized and logical. Many applications fail to receive a high score because the reviewers cannot follow the thought process of the applicant or because parts of the application do not fit together.

Be careful in the use of appendices. Do not use the appendices for information that is required in the body of the application. Be sure to cross-reference all tables and attachments located in the appendices to the appropriate text in the application.

Carefully proofread the application. Misspellings and grammatical errors will impede reviewers in understanding the application. Be sure pages are numbered (including appendices) and that page limits are followed. Limit the use of abbreviations and acronyms, and define each one at its first use and periodically throughout application.

Dated: August 26, 2005.

Mary Lou Valdez,

Deputy Director for Policy, Office of Global Health Affairs.

Cristina V. Beato,

Acting Assistant Secretary for Health, Office of Public Health and Science.

[FR Doc. 05-17590 Filed 9-2-05; 8:45 am]

BILLING CODE 4150-38-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request the Office of Management and Budget (OMB) to reinstate the information collection project: "AHRQ-HRSA Chemical, Biological, Radiological, Nuclear and Explosive (All Hazards) Preparedness Questionnaire for Healthcare Facilities for 2004 (CBRNE)". In accordance with the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(C)(2)(A), AHRQ invites the public to comment on this proposed information collection.

AHRQ obtained a six-month emergency collection approval for the first wave of this information collection.

This reinstatement of the previous clearance approval covers the second wave of the same survey. The respondents will be queried as to their progress in achieving the preparedness goals reported in the first wave.

DATES: Comments on this notice must be received by November 7, 2005.

ADDRESSES: Written comments for the proposed information collection should be submitted to: Cynthia D. McMichael, Reports Clearance Officer, AHRQ, 540 Gaither Road, Room #5022, Rockville, MD 20850.

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Cynthia D. McMichael, AHRQ Reports Clearance Officer, (301) 427-1651.

SUPPLEMENTARY INFORMATION:

Proposed Project

"AHRQ-HRSA Chemical, Biological, Radiological, Nuclear and Explosive (All Hazards) Preparedness Questionnaire for Healthcare Facilities for 2004 (CBRNE)"

The Preparedness Questionnaire is an inventory of the U.S. hospitals which received support for preparedness activities under the HRSA National Bioterrorism Hospital Preparedness Program. This survey instrument is being designed for use by preparedness planners to measure local or regional hospital levels of preparedness for a chemical, biological, radiological, nuclear and explosive (CBRNE) event. One point of contact is designated in each hospital to provide information on a range of topics that have been deemed essential by a panel of nationally-recognized experts on issues related to hospital preparedness for a CBRNE, i.e., an all hazards event.

These topics include facility planning and administration; training and education; communication and notification; patient capacity; staffing and support; isolation and decontaminations; supplies, pharmaceuticals and laboratory support; and surveillance.

The inventory, which was administered in 2004/2005 and will be again in 2006, will provide national, state, and regional levels of preparedness by type of hospital, as well as estimates of bed capacity and emergency increase (surge) capacity. This information will be used to ascertain the progress of the previously queried hospitals in attaining their preparedness goals.

In addition to determination the capacity of the survey instrument to actually collect information needed for local and regional planning, it should also be useful for national planning, program planning, setting priority areas in addressing current and future needs, as well as ensuring that scarce resources are being used in a way that achieves the most impact in preparedness.

Data Confidentiality Provisions

The data will be collected by an independent consulting firm under terms of its contract. The identifiable information about institutions will be kept confidential in accordance with 42 USC 299c-3(c). AHRQ and HRSA will receive only state-level summary data, and not individual hospital responses.

Method of Collection

The preparedness questionnaire will be administered electronically to each hospital via electronic mail. The estimated burden is as follows:

Estimated Annual Respondent Burden

Number of questionnaire recipients	Estimated burden/respondent	Total hours of burden
1479	60 minutes	1479

The estimate burden is based on the completion of a paper version of the questionnaire by a pilot hospital. The more efficient data collection effort enabled by the electronic format has been taken into account in this estimate. The annualized cost to all potential respondents is estimated at \$51,528 Total (\$34.84/hr [average staff time] × 1 hr. × 1479 respondents). Percentage of capital costs, operating costs or maintenance costs are negligible.

A stratified random sample by state will be used in this second wave survey. This second wave (resurvey) is utilizing statistical methods based on baseline data in developing a sampling scheme.

Request for Comments

In accordance with the above cited Paperwork Reduction Act legislation, comments on the AHRQ's and HRSA's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of functions of AHRQ and HRSA, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and costs) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d)

ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: August 12, 2005.

Carolyn M. Clancy,
Director.

[FR Doc. 05-17617 Filed 9-2-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004P-0379]

Determination That Penthrane (Methoxyflurane) Inhalation Liquid, 99.9 Percent, Was Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that Penthrane (methoxyflurane) Inhalation Liquid, 99.9 percent, was withdrawn from sale for reasons of safety or effectiveness. The agency will not accept or approve abbreviated new drug applications (ANDAs) for methoxyflurane inhalation liquid, 99.9 percent.

FOR FURTHER INFORMATION CONTACT: Mary Catchings, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new

drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, drugs are removed from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)).

Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

Penthrane (methoxyflurane) Inhalation Liquid, 99.9 percent, was the subject of NDA 13-056, held by Abbott Laboratories (Abbott). Penthrane is a potent inhalation anesthetic indicated to provide anesthesia for surgical procedures in which total duration of administration is anticipated to be 4 hours or less (not to be used at concentrations that provide skeletal muscle relaxation). Penthrane was also indicated to provide analgesia in obstetrics and in minor surgical procedures and for use by self-administration using hand held inhalers. In the **Federal Register** of August 16, 2001 (66 FR 43017), FDA withdrew approval of NDA 13-056 for Penthrane after Abbott notified the agency that Penthrane was no longer being marketed under NDA 13-056 and requested withdrawal of that application. Penthrane was then moved to the "Discontinued Drug Product List" section of the Orange Book.

In a citizen petition dated August 25, 2004 (Docket No. 2004P-0379/CP1), submitted under § 10.30 (21 CFR 10.30), and in accordance with § 314.161, AAC Consulting Group requested that the agency determine whether Penthrane (methoxyflurane) Inhalation Liquid, 99.9 percent, was withdrawn from sale for reasons of safety or effectiveness.

We have carefully reviewed our files for records concerning the withdrawal of Penthrane (methoxyflurane)

Inhalation Liquid, 99.9 percent, including the NDA file for this drug product. We have also independently evaluated relevant literature and data for possible postmarketing adverse event reports. FDA has determined under §§ 314.161 and 314.162(a)(2) that Penthrane (methoxyflurane) Inhalation Liquid, 99.9 percent, was withdrawn from sale for reasons of safety. FDA's review shows that methoxyflurane, a volatile anesthetic agent, is associated with serious, irreversible, and even fatal nephrotoxicity and hepatotoxicity in humans. FDA has also reviewed the latest approved labeling for Penthrane and has determined that this labeling is inadequate. FDA believes that the risks of toxicity outweigh any potential benefits if methoxyflurane is used according to the latest approved labeling. Since the initial approval of Penthrane in 1962, with a subsequent finding of efficacy in the **Federal Register** of December 11, 1981 (46 FR 60652), alternative safe and effective anesthetics have been approved by FDA and entered the market. FDA has determined that new clinical studies are necessary before methoxyflurane could be considered for reintroduction to the market. The agency has determined, under § 314.161, that Penthrane (methoxyflurane) Inhalation Liquid, 99.9 percent was withdrawn from sale for reasons of safety. Therefore, Penthrane (methoxyflurane) Inhalation Liquid, 99.9 percent, will be removed from the list of drug products published in the Orange Book. FDA will not accept or approve ANDAs that refer to this drug product.

Dated: August 29, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05-17559 Filed 9-2-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2005M-0158, 2005M-0159, 2005M-0129, 2005M-0160, 2005M-0130, 2005M-0151, 2005M-0117, 2005M-0118, 2005M-0241, 2005M-0191, 2005M-0192, 2005M-0193, 2005M-0270]

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