

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.

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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Determination That Penthrane (Methoxyflurane) Inhalation Liquid, 99.9 Percent, Was Withdrawn From Sale for Reasons of Safety or Effectiveness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Food and Drug Administration (FDA) has determined that Penthrane (methoxyflurane) Inhalation Liquid, 99.9 percent, was withdrawn from sale for reasons of safety or effectiveness.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.

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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

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 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: Thinh Nguyen, Center for Devices and Radiological Health (HFZ-402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2186.

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 Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from April 1, 2005, through June 30, 2005. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM APRIL 1, 2005, THROUGH JUNE 30, 2005.

PMA No./Docket No.	Applicant	TRADE NAME	Approval Date
P030040/2005M-0158	Bayer Healthcare, LLC	ADVIA CENTAUR HBC IGM READY PACK REAGENTS, ADVIA CENTAUR HBC IGM QUALITY CONTROL MATERIAL	August 6, 2004
P020055/2005M-0159	Ventana Medical Systems, Inc.	VENTANA MEDICAL SYSTEMS PATHWAY ANTI-C-KIT (9.7) PRIMARY ANTIBODY	August 11, 2004
P040018/2005M-0129	Bayer Healthcare, LLC	ADVIA CENTAUR HAV IGM READY PACK REAGENTS, ADVIA CENTAUR HAV IGM QUALITY CONTROL MATERIAL	December 22, 2004
P040030/2005M-0160	BioGenex Laboratories, Inc.	INSITE HER-2/NEU KIT	December 22, 2004
P030052/2005M-0130	Vysis, Inc.	UROVYSION BLADDER CANCER KIT	January 24, 2005
P930016(S20)/2005M-0151	VISX, Inc.	STAR S4 IR EXCIMER LASER SYSTEM WITH VARIABLE SPOT SCANNING (VSS)	March 17, 2005
P040020/2005M-0117	Alcon Research, Ltd.	ACRYSOF RESTOR APODIZED DIFFRACTIVE OPTIC POSTERIOR CHAMBER IOL	March 21, 2005
P040024/2005M-0118	Medicis Aesthetics Holdings, Inc.	RESTYLANE INJECTABLE GEL	March 25, 2005
P040026/2005M-0241	Medispec, Ltd.	ORTHOSPEC EXTRACORPOREAL SHOCK WAVE THERAPY DEVICE	April 1, 2005
P040034/2005M-0191	Confluent Surgical, Inc.	DURASEAL DURAL SEALANT SYSTEM	April 7, 2005
P040016/2005M-0192	Boston Scientific Corp.	BOSTON SCIENTIFIC CORPORATION LIBERTE MONORAIL AND OVER-THE-WIRE CORONARY STENT SYSTEMS	April 12, 2005
P030037/2005M-0193	Biotronik, Inc.	RITHRON-XR CORONARY STENT SYSTEM	April 29, 2005
P030049/2005M-0270	Bayer Healthcare, LLC	ADVIA CENTAUR HBS AG READY PACK REAGENTS, ADVIA CENTAUR HBS AG CONFIRMATORY READY PACK REAGENTS, AND ADVIA CENTAUR HBS AG QUALITY CONTROL MATERIAL	May 31, 2005

II. Electronic Access

Persons with access to the Internet may obtain the documents at <http://www.fda.gov/cdrh/pmapage.html>.

Dated: August 22, 2005.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D-0324]

International Conference on Harmonisation; Draft Guidance on M5 Data Elements and Standards for Drug Dictionaries; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "M5 Data Elements and Standards for Drug Dictionaries." The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guidance describes the data elements and standards that ICH recommends be made available to interested parties to assist in the development and maintenance of drug dictionaries. The draft guidance is intended to facilitate the exchange and practical use of medicinal product information at the international level, such as with postmarketing safety reporting.

DATES: Submit written or electronic comments on the draft guidance by October 21, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training, and

Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. The draft guidance may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800. Send two self-addressed adhesive labels to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Randy Levin, Center for Drug Evaluation and Research (HFD-001), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7784; or Ann Schwartz, Center for Biologics Evaluation and Research (HFM-475), Food and Drug Administration, 1401 Rockville Pike, rm. 300N, Rockville, MD 20832, 301-827-3070.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4480.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug

Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of ICH's sponsors and IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In May 2005, the ICH Steering Committee agreed that a draft guidance entitled "M5 Data Elements and Standards for Drug Dictionaries" should be made available for public comment. The draft guidance is the product of the M5 Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the M5 expert working group.

The draft guidance describes the data elements that ICH recommends be made available to interested parties to assist in the development and maintenance of drug dictionaries. The draft guidance outlines each data element and provides recommended standards for the data elements. The draft guidance addresses medicinal products (drugs and biologics) and is intended to accomplish the following goals:

- Improve the exchange of medicinal product information,
- Improve consistency in evaluating and comparing medicinal products for postmarketing surveillance activities,
- Provide consistent terminology for the health care community, and
- Reduce administrative burdens for the pharmaceutical industry when complying with different regional regulatory requirements.

The draft guidance refers to approved medicinal products. The draft guidance does not apply to homeopathic medicinal products or investigational medicinal products. The draft guidance does not cover the establishment and maintenance of a drug dictionary.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on M5 data elements and standards for drug dictionaries. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.