

that is intended to use a direct current to introduce ions of soluble salts or other drugs into the body and induce sweating for diagnostic or other uses. If the iontophoresis device is intended for use in the diagnosis of cystic fibrosis or another intended use and the labeling of the drug intended for use with the device bears adequate directions for the device's use with that drug, the device is categorized as class II. An iontophoresis device that is intended to introduce ions of soluble salts or other drugs into the body for other purposes is categorized as class III.

In the **Federal Register** of August 22, 2000, FDA proposed to amend the physical medicine devices regulations to remove the class III (premarket approval) iontophoresis device identification. FDA proposed this action because it believed that there were no preamendments iontophoresis devices marketed for uses other than those described in the class II identification. FDA expected that manufacturers of those devices currently in class III would be able to relabel their devices to meet the class II identification.

In response to the August 2000 proposed rule, FDA received seven comments. Several comments disagreed with FDA's assertion that no class III preamendments iontophoresis devices existed. Two comments were confused as to whether the requirement that a drug used with an iontophoresis device bear adequate directions for use with that specific device applies to the diagnosis of cystic fibrosis or applies only to other uses. Two comments asserted that the assumption that there are differences in iontophoresis devices that would warrant linking a particular device to a particular drug is in error, and suggested that FDA should consider reclassification of iontophoresis devices into either class I or class II as drug delivery systems comparable to syringes and pumps. In contrast, another comment rejected what it perceived as the implication that all iontophoresis drug delivery systems were the same and that any iontophoresis device could be relabeled to reference any drug approved for iontophoretic administration, whether or not the drug had actually been tested for use with that particular device.

FDA is issuing this document to provide interested persons with an opportunity to submit any new information concerning the safety and effectiveness of the iontophoresis device. After FDA reviews any information that the agency receives in response to this document, FDA will decide whether the agency should go forward with the reclassification of

those iontophoresis devices currently in class III and whether a panel meeting is necessary before taking any action.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Any received information may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 25, 2004.

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. 2004N-0087]

Draft Guidance for Industry on Listed Drugs, 30-Month Stays, and Approval of Abbreviated New Drug Applications and 505(b)(2) Applications Under Hatch-Waxman, as Amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003—Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Listed Drugs, 30-Month Stays, and Approval of ANDAs and 505(b)(2) Applications Under Hatch-Waxman, as Amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003—Questions and Answers." This draft guidance follows the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173) (MMA) on December 8, 2003. In part, this guidance satisfies FDA's obligation under that law to clarify the definition of "listed drug" for persons who wish to submit a change (i.e., an amendment or supplement) to an abbreviated new drug application (ANDA). The guidance explains when a change to an

application should reference a drug different from the drug listed in the original ANDA, requiring the change to be made through an entirely new application.

In addition to the definition of "listed drug," the draft guidance clarifies certain other provisions of the MMA that significantly change the law that existed before the MMA's enactment. These include changes regarding 30-month stays and approval of ANDAs and new drug applications submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (505(b)(2) applications). The draft guidance also explains the effective dates that apply to the MMA's provisions.

DATES: Submit written or electronic comments on the draft guidance by February 2, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: 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. Send one self-addressed adhesive label to assist that office in processing your requests. 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>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Martin Shimer, Center for Drug Evaluation and Research (HFD-615), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855 301-827-5710.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Listed Drugs, 30-Month Stays, and Approval of ANDAs and 505(b)(2) Applications Under Hatch-Waxman, as Amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003—Questions and Answers." On December 8, 2003, the MMA was signed into law. Among other things, Title XI of that law, "Access to Affordable Pharmaceuticals," states that guidance will be issued to define the term "listed drug" with respect to amendments and supplements to ANDAs. This guidance is necessary because the MMA specifies that, "An

applicant may not amend or supplement an [ANDA] to seek approval of a drug referring to a different listed drug from the listed drug identified in the application as submitted to the Secretary" (MMA, Title XI, section 1101(a)(1)(B)). In part, the draft guidance clarifies the definition of "listed drug" in the context of ANDAs as directed by the MMA. Portions of the guidance addressing "listed drug" are expected to be of use to sponsors who are contemplating submitting an amendment or supplement to an existing ANDA rather than submitting a new application. The draft guidance should aid these sponsors in determining when to reference a different listed drug and, thus, when to submit a new application rather than an amendment or supplement. A situation that is not considered in this guidance is that where a pending ANDA was submitted referencing a petition approved under section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(j)(2)(C)), and another application is approved for the product described in the petition before the pending ANDA is approved. FDA has not completed its analysis of this situation, and therefore the draft guidance does not cover it.

In addition to the definition of "listed drug," the draft guidance clarifies certain other significant changes made by the MMA to provisions of the act that were originally added by the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) (Hatch-Waxman). These include changes made by the MMA with respect to the availability and termination of 30-month stays of approval on ANDAs and 505(b)(2) applications under section 505(j)(5)(B)(iii) and 505(c)(3)(C) of the act, respectively, and to requirements for notice of patent certifications described by section 505(b)(2)(A)(iv) and 505(j)(2)(A)(vii)(IV) of the act (paragraph IV certifications). The draft guidance also clarifies the applicability of certain changes made by the MMA regarding the period described by section 505(j)(5)(B)(iv) of the act during which ANDAs with paragraph IV certifications that were not the first to be submitted cannot be approved (180-day exclusivity). Finally, this guidance explains the effective dates that apply to the MMA's amendments. FDA is aware that these changes are complex and include significant departures from previous law. The agency therefore wishes to provide guidance to industry to clarify these amendments.

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 the definition of "listed drug" for amendments and supplements to ANDAs, and on 30-month stays and certain other matters related to the approval of ANDAs and 505(b)(2) applications. 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.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: October 18, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[USCG-2004-16860]

Gulf Landing, LLC Deepwater Port License Application

AGENCY: Coast Guard, DHS, and Maritime Administration, DOT.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The U.S. Coast Guard (USCG) and the U.S. Maritime Administration (MARAD) will hold a public hearing to receive information relevant to the issuance or denial of the requisite federal license for the proposed Gulf

Landing, LLC (Gulf Landing) Deepwater Port project. The proposed Gulf Landing Deepwater Port would be located in West Cameron Lease Block Number 213, approximately 38 miles south of Cameron, Louisiana. We encourage interested individuals and organizations to attend the public hearing and submit comments. We also seek comments from anyone unable to attend the public hearing. In conjunction with the public hearing, the USCG and MARAD will also hold an informational open house regarding the proposed Gulf Landing Deepwater Port project.

DATES: The public hearing will be held on Thursday, November 18, 2004, from 5 to 7 p.m., in New Orleans, Louisiana. The informational open house will be held on Thursday, November 18, 2004, from 3 to 4:30 p.m., at the same location in New Orleans, Louisiana. The public hearing will continue beyond 7 p.m. if necessary to ensure all individuals present at that time who wish to comment have an opportunity to do so.

Comments intended for inclusion in the public docket [USCG-2004-16860] must reach the Docket Management Facility on or before January 3, 2005.

ADDRESSES: The public hearing and informational open house will be held at the following location: Hyatt Regency New Orleans Hotel, Poydras at Loyola Avenue, New Orleans, Louisiana 70113, telephone 504-561-1234.

You may submit comments identified by Coast Guard docket number USCG-2004-16860 to the Docket Management Facility at the U.S. Department of Transportation. To avoid duplication, please use only one of the following methods:

- (1) *Web Site:* <http://dms.dot.gov>.
- (2) *Mail:* Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590-0001.
- (3) *Fax:* 202-493-2251.
- (4) *Delivery:* Room PL-401 on the Plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

(5) Federal eRulemaking Portal: <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: For further information concerning this notice, the Gulf Landing Deepwater Port license application, or the public hearing or informational open house, contact LCDR Derek Dostie, U.S. Coast Guard at (202) 267-0662 or ddostie@comdt.uscg.mil. If you have questions on viewing or submitting material to the docket, call Andrea M.