Board of Governors of the Federal Reserve System, April 2, 1998.

William W. Wiles,

Secretary of the Board.

[FR Doc. 98-9072 Filed 4-6-98; 8:45 am]

BILLING CODE 6210-01-F

FEDERAL RESERVE SYSTEM

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Board of Governors of the Federal Reserve System.

TIME AND DATE: 11:00 a.m., Monday, April 13, 1998.

PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Joseph R. Coyne, Assistant to the Board; 202-452-3204.

SUPPLEMENTARY INFORMATION: You may call 202-452-3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Wed site at http://www.bog.frb.fed.us for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: April 3, 1998.

William W. Wiles,

Secretary of the Board.

[FR Doc. 98-9268 Filed 4-3-98; 3:48 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N-0182]

Bulk Drug Substances To Be Used in Pharmacy Compounding; Request for Nominations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for nominations.

SUMMARY: The Food and Drug Administration (FDA) is preparing to develop a list of bulk drug substances (bulk drugs) that may be used in pharmacy compounding that do not have a United States Pharmacopeia (USP) or National Formulary (NF) monograph and are not components of approved drugs. FDA is taking this action in accordance with provisions in the Food and Drug Administration Modernization Act of 1997 (FDAMA). To identify candidates for this bulk drugs list, FDA is encouraging interested groups and individuals to nominate specific bulk drug substances and is describing the information that should be provided to the agency in support of each nomination.

DATES: Nominations must be received by June 8, 1998, to receive consideration for inclusion on the bulk drugs list. Nominations received after this date will receive consideration for subsequent amendments to the list.

ADDRESSES: Send nominations to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Robert J. Tonelli, Center for Drug Evaluation and Research (HFD-332), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-0101.

SUPPLEMENTARY INFORMATION: President Clinton signed FDAMA (Pub. L. 105-115) into law on November 21, 1997. One of the issues addressed in this new legislation is the applicability of the Federal Food, Drug, and Cosmetic Act (the act) to the practice of pharmacy compounding. Compounding involves a process whereby a pharmacist or physician combines, mixes, or alters ingredients to create a customized medication for an individual patient. Section 127 of FDAMA, which adds section 503A to the act (21 U.S.C. 353a), describes the circumstances under which compounded drugs qualify for exemptions from certain adulteration, misbranding, and new drug provisions of the act. Section 127 becomes effective 1 year from the date of the FDAMA's enactment (section 503A(b) of the act).

Section 127 contains several restrictions regarding the bulk drug substances[1] that may be used as ingredients in compounding and still qualify for the applicable exemptions. It provides, among other things, that such substances must comply with the standards of an applicable USP or NF monograph, if one exists, and the USP chapter on pharmacy compounding; if a monograph does not exist, they must be components of drugs approved by FDA; and if neither of those criteria are satisfied, they must appear on a list that FDA develops and issues through regulations (section 503A(b)(1)(A)(i)(I) through (b)(1)(A)(i)(III) of the act).

In accordance with the bulk drug provisions in section 127, FDA is preparing to develop a list of bulk drug substances that may be used in compounding that do not have a USP or NF monograph and are not components of approved drugs. To identify candidates for this list, FDA is seeking public input in the form of specific bulk drug nominations. All interested groups and individuals are encouraged to nominate specific bulk drug substances for inclusion on the list. FDA intends for this nomination process to serve as its principal means of identifying list candidates. After evaluating the nominations and, as required by Congress, consulting with the United States Pharmacopeial Convention, Inc., and an advisory committee on compounding (section 503A(d) of the act), FDA will issue the list as a regulation under notice-and-comment rulemaking procedures.

Nominations should include the following information about the bulk drug substance being nominated and the product(s) that will be compounded using such substance. If the information requested is unknown or unavailable, that fact should be noted accordingly.

Bulk Drug Substance

- Ingredient name;
- Chemical name;
- Common name(s);
- Chemical grade or description of the strength, quality, and purity of the ingredient;
- Information about how the ingredient is supplied (e.g., powder, liquid);
- Information about recognition of the substance in foreign pharmacopeias and the status of its registration(s) in other countries, including whether information has been submitted to USP for consideration of monograph development; and
- A bibliography of available safety and efficacy data[2], including any

[1] The term "bulk drug substance" is defined in FDA's regulations at 21 CFR 207.3(a)(4) and incorporated in section 127 of FDAMA to mean "any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances."

[2] FDA recognizes that the available safety and efficacy data is unlikely to be of the same type, amount, or quality as would be required to support a new drug application, but this fact will not preclude a bulk drug substance from consideration for inclusion on the list.

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relevant peer reviewed medical literature.

Compounded Product

- Information about the dosage form(s) into which the drug substance will be compounded (including formulations);
- Information about the strength(s) of the compounded product(s);
- Information about the anticipated route(s) of administration of the compounded product(s);
- Information about the past and proposed use(s) of the compounded product(s), including the rationale for its use or why the compounded product(s), as opposed to a commercially available product, is necessary;
- Available stability data for the compounded product(s); and
- Additional relevant information.

FDA cannot guarantee that all drugs nominated during the comment period will be considered for inclusion on the first published bulk drugs list. Nominations received during the comment period that are supported by the most complete and relevant information, as set forth previously, will likely be evaluated first. Nominations that are not evaluated during this first phase will receive consideration for list amendments, as the development and issuance of this list will be an ongoing process. Individuals and organizations also will be able to petition FDA to make additional list amendments after the list is published.

Interested groups and individuals should submit their bulk drug substance nominations to the Dockets Management Branch (address above). Two copies of the nominations are to be submitted, except that individuals may submit one copy. However, individuals are encouraged to consolidate their submissions through professional organizations. Nominations are to be identified with the docket number found in brackets in the heading of this document. Received nominations and supporting information will be treated as public information and will be available for inspection at the above address between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 1, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98-9037 Filed 4-6-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Grassroots Regulatory Partnership Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA), (Office of Regulatory Affairs, Dallas District Office, Kansas District Office, Atlanta District Office, Nashville District Office, and New Orleans District Office) is announcing the following workshop: Grassroots Regulatory Partnership Workshop. The topic to be discussed is FDA regulatory requirements for the food-producing aquaculture industry. The purpose of the workshop is to promote open dialogue between FDA, the aquaculture industry, related trade associations, other government agencies, academia, and any other interested stakeholders on drug use, good manufacturing practices (GMP's) in processing systems, the seafood hazard analysis critical control point (HACCP) regulations, and any related topics.

Date and Time: The workshop will be held on Tuesday, May 12, 1998, 8:30 a.m. to 5 p.m. Registration will close on April 28, 1998.

Location: The workshop will be held at the Crowne Plaza—Downtown Jackson, 200 Amite St., Jackson, MS 39201, 601-969-5100, or 800-227-6963.

Contact: Richard D. Debo, Food and Drug Administration, New Orleans District Office (HFR-SE440), 4298 Elysian Fields Ave., New Orleans, LA 70122, 504-589-7166, FAX 504-589-4657.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) to the contact person by April 28, 1998. There is no registration fee for this workshop. Space is limited; therefore, interested parties are encouraged to register early.

If you need special accommodations due to a disability, please contact Richard D. Debo at least 7 days in advance.

SUPPLEMENTARY INFORMATION: In 1995 President Clinton directed the heads of all Federal regulatory agencies to carry out a four step regulatory reinvention initiative. The basic idea of the President's initiative was to replace adversarial approaches with a partnership approach based on clear goals and cooperation. The President specifically directed top management from regulatory agencies to hold "grassroots" workshops with regulated industry, and this workshop is designed to meet that requirement.

Priority will be given to those businesses located in the Dallas, Kansas, Atlanta, Nashville, and New Orleans Districts, which include the States of: Oklahoma, Texas, Arkansas, Iowa, Nebraska, Missouri, Kansas, Georgia, North Carolina, South Carolina, Tennessee, Alabama, Louisiana, and Mississippi. Companies located outside these States may register to attend the workshop and will be accepted if space is available.

Dated: March 20, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98-8970 Filed 4-6-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Marais des Cygnes Comprehensive Conservation Plan; Notice of Availability

SUMMARY: Pursuant to the Refuge Improvement Act of 1997, the U.S. Fish and Wildlife Service has published the Marais des Cygnes Comprehensive Conservation Plan. This plan describes how the FWS intends to manage the Marais des Cygnes NWR for the next 10-15 years.

ADDRESSES: A summary of the plan or the complete plan may be obtained by writing to U.S. Fish and Wildlife Service, Attn: Barbara Shupe, P.O. Box 25486 DFC, Denver, CO 80225 or U.S. Fish and Wildlife Service, Flint Hills NWR, P.O. Box 128, Hartford, KS 66854. Unless the full plan is specifically requested, the summary will be sent.

FOR FURTHER INFORMATION CONTACT: Adam Misztal, U.S. Fish and Wildlife Service, P.O. Box 25486 DFC, Denver, CO 80225, 303/236-8145 extension 607; fax 303/236-8680.

SUPPLEMENTARY INFORMATION: The plan calls for the restoration of native bottomland forest, prairie, and savannah. Wetlands would also be created and maintained on the Refuge. In addition, up to 1,500 acres would be farmed on the Refuge to reduce crop depredation on private lands and as a tool for native vegetation restoration. Various forms of wildlife-dependent recreation would also be provided for.