

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.

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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.

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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.