

engineer services. This notice announces modifications to GSA's solicitation practices under the demonstration program based on a review of the agency's performance during the period from July 1, 1994 to June 30, 1995. Modifications to solicitation practices are outlined in the Supplementary Information section below and apply to solicitations issued on or after October 1, 1995.

EFFECTIVE DATE: October 1, 1995.

FOR FURTHER INFORMATION CONTACT: Tom Wisnowski, Office of GSA Acquisition Policy, (202) 501-1224.

SUPPLEMENTARY INFORMATION:

Procurements of construction or trash/garbage collection with an estimated value of \$25,000 or less will be reserved for emerging small business concerns in accordance with the procedures outlined in the interim policy directive issued by the Office of Federal Procurement Policy (58 FR 13513, March 11, 1993).

Procurements of construction or trash/garbage collection with an estimated value that exceeds \$25,000 by GSA contracting activities will be made in accordance with the following procedures:

Construction Services in Groups 15, 16, and 17

Procurements for all construction services (except solicitations issued by GSA contracting activities in Regions 1, 2, 3, 4, 5, 8, 10, and the National Capital Region) in SIC Group 15, shall be conducted on an unrestricted basis.

Procurements for construction services in SIC Group 15 issued by GSA contracting activities in Regions 1, 2, 3, 4, 5, 8, 10, and the National Capital Region shall be set aside for small business when there is a reasonable expectation of obtaining competition from two or more small businesses. If no expectation exists, the procurements will be conducted on an unrestricted basis.

Region 1 encompasses the states of Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island and Vermont.

Region 2 encompasses the states of New Jersey, New York, and the territories of Puerto Rico and the Virgin Islands.

Region 3 encompasses the states of Pennsylvania, Delaware, West Virginia, Maryland (except Montgomery and Prince Georges counties), and Virginia (except the city of Alexandria and the counties of Arlington, Fairfax, Loudoun, and Prince William).

Region 4 encompasses the states of Alabama, Florida, Georgia, Kentucky,

North Carolina, South Carolina, Mississippi, and Tennessee.

Region 5 encompasses the states of Illinois, Indiana, Ohio, Michigan, Minnesota, and Wisconsin.

Region 8 encompasses the states of Colorado, Montana, North Dakota, South Dakota, Utah, and Wyoming.

Region 10 encompasses the states of Alaska, Idaho, Oregon, and Washington.

The National Capital Region encompasses the District of Columbia, Montgomery and Prince Georges counties in Maryland, and the city of Alexandria and the counties of Arlington, Fairfax, Loudoun, and Prince William in Virginia.

Trash/Garbage Collection Services in PSC S205

Procurements for trash/garbage collection services in PSC S205 will be conducted on an unrestricted basis.

Architect-Engineer Services (all PSC Codes Under the Demonstration Program)

Procurements for all architect-engineer services (except procurements issued by contracting activities in GSA Regions 2, 3, 4, 5, 9, and the National Capital Region) shall be conducted on an unrestricted basis. Procurements for A-E services issued by contracting activities in Regions 2, 3, 4, 5, 9, and the National Capital Region shall be set aside for small business when there is a reasonable expectation of obtaining competition from two or more small businesses. If no expectation exists, the procurements may be conducted on an unrestricted basis.

Region 2 encompasses the states of New Jersey, New York, and the territories of Puerto Rico and the Virgin Islands.

Region 3 encompasses the states of Pennsylvania, Delaware, West Virginia, Maryland (except Montgomery and Prince Georges counties), and Virginia (except the city of Alexandria and the counties of Arlington, Fairfax, Loudoun, and Prince William).

Region 4 encompasses the states of Alabama, Florida, Georgia, Kentucky, North Carolina, South Carolina, Mississippi, and Tennessee.

Region 5 encompasses the states of Illinois, Indiana, Ohio, Michigan, Minnesota, and Wisconsin.

Region 9 encompasses the states of Arizona, California, Hawaii, and Nevada.

The National Capital Region encompasses the District of Columbia, Montgomery and Prince Georges counties in Maryland, and the city of Alexandria and the counties of

Arlington, Fairfax, Loudoun, and Prince William in Virginia.

Non-Nuclear Ship Repair

GSA does not procure non-nuclear ship repairs.

Dated: August 24, 1995.

Ida M. Ustad,

Associate Administrator for Acquisition Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95N-0270]

Drug Export; Anzemet (Dolasetron Mesilate) Bulk Drug Substance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Marian Merrell Dow Inc., has filed an application requesting conditional approval for the export of Anzemet (dolasetron Mesilate) Bulk Drug Substance to Italy for the preparation and packaging of the following injectable dose strengths 12.5 milligrams (mg), 25 mg, 50 mg, 100 mg, and 200 mg for transshipment to the United Kingdom.

ADDRESSES: Relevant information on this application may be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human drugs under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: James E. Hamilton, Center for Drug Evaluation and Research (HFD-310), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301-594-3150.

SUPPLEMENTARY INFORMATION: The drug export provisions in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382) provide that FDA may approve applications for the export of drugs that are not currently approved in the United States. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30

days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the **Federal Register** within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that Marian Merrell Dow Inc., Marian Park Dr., P.O. Box 9627, Kansas City, MO 64134-0627, has filed an application requesting conditional approval for the export of Anzemet (dolasetron Mesilate) Bulk Drug Substance to Italy for the preparation and packaging of the following injectable dose strengths 12.5 mg, 25 mg, 50 mg, 100 mg, and 200 mg for transshipment to the United Kingdom. Anzemet (dolasetron Mesilate) injection is indicated for nausea and vomiting in patients receiving initial and repeat courses of cancer chemotherapy (including high dose cisplatin) or radiotherapy and for post operative nausea and vomiting. The application was received and filed in the Center for Drug Evaluation and Research on August 8, 1995, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by September 11, 1995, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Drug Evaluation and Research (21 CFR 5.44).

Dated: August 11, 1995.

Betty L. Jones,

Deputy Director, Office of Compliance, Center for Drug Evaluation and Research.

[FR Doc. 95-21453 Filed 8-29-95; 8:45 am]

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[Docket No. 95S-0193]

Pharmacology/Toxicology Electronic Submissions Pilot Project

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the Pharmacology/Toxicology (P/T) Electronic Submissions Pilot Project developed by the Center for Drug Evaluation and Research (CDER). This project is intended to increase the efficiency of both the investigational new drug application (IND) and the new drug application (NDA) review processes by providing for the electronic submission of preclinical P/T study reports. CDER is requesting that interested sponsors submit, on a voluntary basis, electronic copies of P/T study reports containing complete text and graphic material for review in word processor format, in addition to paper submissions.

FOR FURTHER INFORMATION CONTACT:

Regarding general information about the pilot project: Joseph F. Contrera, Center for Drug Evaluation and Research (HFD-400), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4750.

Regarding technical information about participation in the pilot program: Patricia A. Sylvia, Center for Drug Evaluation and Research (HFD-72), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3695.

SUPPLEMENTARY INFORMATION: CDER is exploring ways in which electronic submissions can be used to increase the efficiency of the drug review process. A key part of this process is the review of preclinical animal studies, most of which are conducted during the IND phase of the application. CDER has established a pilot project requesting that sponsors voluntarily submit electronic copies of P/T study reports, in addition to paper submissions. These reports would contain complete text and graphic material for review in word processor format. Electronic submissions of P/T study reports would allow for efficient storage and the capacity to retrieve, copy, and print pertinent sections of submissions for review.

This pilot project is expected to be most useful during the IND review process because the large proportion of preclinical P/T studies is submitted during this period. The agency believes that increasing the efficiency of the IND

review process will have a positive effect on the NDA review process. If this pilot project is successful, CDER may consider acceptance of only electronic submissions. In the **Federal Register** of August 31, 1994 (59 FR 45160), FDA published a proposed rule entitled "Electronic Signatures; Electronic Records." This pilot project is consistent with the goals of the proposed rule.

A description of the pilot project, as well as the general format and media specifications for electronic submissions, follows:

The Center for Drug Evaluation and Research (CDER) Pharmacology/Toxicology (P/T) Electronic Submissions

I. Background

CDER is exploring ways in which electronic submissions can be used to increase the efficiency of the drug review process. A key part of this process is the review of preclinical animal studies, most of which are conducted during the IND phase of the application. The Information Technology (IT) Subcommittee of the CDER Pharmacology/Toxicology Coordinating Committee (the P/T IT Subcommittee) is responsible for furthering the concept of electronic submissions for P/T reviews. In November 1994, after discussions between FDA and the Pharmaceutical Research and Manufacturers of America, three firms agreed to submit electronic preclinical P/T reports to CDER. In addition, CDER optically scanned P/T reports that were submitted in paper form, prepared reviews of these submissions electronically, and evaluated the utility of receiving the P/T submissions electronically. As a result of this experience, space has been allocated on the CDER Local Area Network (LAN) for P/T submissions and reviews, and the P/T IT Subcommittee agreed to solicit additional preclinical P/T electronic submissions from sponsors.

Each CDER reviewer is responsible for many IND's and NDA's that are in various stages of development and assigned different priorities. As a result, study reports may be stored in reviewers' offices for considerable periods of time until they can be reviewed. In addition, reviews often contain the results of multiple studies from amendments to an IND submitted at different times. This requires the storage, retrieval, collation, and merging of information from several studies into a single review. Electronic submissions of P/T reports would allow for efficient storage and the capacity to retrieve, copy, and print pertinent sections of submissions for review.

II. Objectives of Electronic Submission Pilot Project

A. Facilitate the Rapid and Convenient Retrieval of Information Contained in Submissions and Minimize Storage Space

A major time-consuming task for reviewers is searching through the large volume of paper submissions to find relevant documents when they are needed. Electronic documents and appropriate document