

which subpopulations are exposed to a product. The draft guidance also does not discuss increasing the total number of participants or members of a subpopulation in clinical trials.

This draft guidance contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The collection of information in sections III and IV of this draft guidance are approved under OMB control number 0910–0014.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on how to collect race and ethnicity data in certain clinical trials for FDA regulated products. 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persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of any 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 The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.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>, <http://www.fda.gov/cber/guidelines.htm>, or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: January 24, 2003.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 03–2162 Filed 1–29–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NM–090–03–9971–EK]

Conservation Helium Sales

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice implementing first Conservation Helium sale.

SUMMARY: The purpose of this action is to implement the terms of the Helium Privatization Act (HPA) of 1996 dealing with the disposal of the Conservation Helium reserve. The Act requires the Department of the Interior *to offer for sale*, beginning no later than 2005, a portion of the Conservation Helium stored underground at the Cliffside Field north of Amarillo, Texas. The Department of the Interior in consultation with the private helium industry has determined that private companies with refining capacity along the crude helium pipeline will need a supply of helium in excess of that available from their own storage accounts and that available from crude helium extractors in the region, and that given the current market, Conservation Helium sold in this sale will likely minimize market disruption. The Bureau just concluded a 30-day comment period in which eight comments were received. The comments were generally supportive with mainly long-term concerns expressed. The Bureau made some minor modifications to address concerns expressed by those comments.

DATES: Submit bids and other documentation as required in notice on or before March 3, 2003.

ADDRESSES: You may submit your bids and other documentation as required in this notice to the Bureau of Land Management, Amarillo Field Office, 810 S. Fillmore, Suite 500, Amarillo, TX 79101, Attention: Crude Helium Sale.

FOR FURTHER INFORMATION CONTACT: Timothy R. Spisak, (806) 356–1002. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

1.01 What Is the Purpose of the Sale?

The purpose of this sale is to begin implementation of the terms of the Helium Privatization Act (HPA) of 1996 dealing with the disposal of the Conservation Helium reserve. The Act requires the Department of the Interior *to offer for sale*, beginning no later than 2005, a portion of the Conservation Helium stored underground at the Cliffside Field north of Amarillo, TX. The Department of the Interior in consultation with the private helium industry has determined that private companies with refining capacity along the crude helium pipeline will need a

supply of helium in excess of that available from their own storage accounts and that available from crude helium extractors in the region. This is the first of 12 annual sales that the Department will conduct to dispose of the Conservation Helium stored underground at the Cliffside Field. The annual sales are being conducted in a manner intended to prevent pure helium market disruptions from occurring to end users; shortages of crude helium to pure helium refiners; and an oversupply of crude helium on the market for crude helium extractors. This first sale will be used to test the disposal process with subsequent sales adjusted as needed.

1.02 What Terms Do I Need To Know To Understand This Sale?

Allocated Sale—That portion of the annual sale volume of Conservation Helium that will be set aside for purchase by the crude helium refiners.

Annual Conservation Helium Sale—The sale of a certain volume of Conservation Helium to private entities conducted annually beginning no later than 2005.

Bidder—Any entity or person who submits a request for purchase of a volume of the annual Conservation Helium sale and has met the qualifications contained in part 1.05 in this notice.

BLM—The Bureau of Land Management.

Conservation Helium—The crude helium purchased by the U.S. Government under the authority of the Helium Act of 1960 and stored underground in the Cliffside Field.

Crude Helium—A partially refined gas containing about 70 percent helium and 30 percent nitrogen. However, the helium concentration may typically vary from 50 to 95 percent.

Crude Helium Refiners—Those entities with a capability of refining crude helium and having a connection point on the crude helium pipeline and a valid helium storage contract as of the date of a Conservation Helium sale.

Excess Volumes—Allocated sale volumes not requested by the crude helium refiners.

Helium Storage Contract—A contract between the BLM and a private entity allowing the private entity to store crude helium in underground storage at the Cliffside Field.

HPA—The Helium Privatization Act of 1996.

In-Kind Crude Helium—Conservation Helium purchased by private refiners in exchange for like amounts of pure helium sold to Federal agencies and