

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Submitting Marketing Applications According to the ICH/CTD Format; General Considerations." This guidance provides general guidance on how to organize new drug applications (NDAs), abbreviated new drug applications (ANDAs) and biologics license applications (BLAs) based on the International Conference on Harmonisation (ICH) M4 guidance on organizing the Common Technical Document (CTD) for the registration of pharmaceuticals for human use.

DATES: Submit written or electronic comments on the draft guidance by November 5, 2001. 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ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training and Manufacturers Assistance (HFMA-40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-3844, FAX 888-CBERFAX. Send two self-addressed adhesive labels to assist the office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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:

Randy Levin, Center for Drug Evaluation and Research (HFD-001), Food and Drug Administration, 1451 Rockville Pike, Rockville, MD 20857, 301-594-5400; or

Robert Yetter, Center for Biologics Evaluation and Research (HFMA-25), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0373.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Submitting Marketing Applications According to the ICH/CTD Format; General Considerations." This guidance is intended to supplement the ICH M4 guidances on quality, safety, and

efficacy, which were signed off at step 4 of the ICH process in October 2000. Final versions of the M4 guidances on organizing the CTD will be available soon. This general considerations guidance applies to NDAs, ANDAs, and BLAs for both new molecular entities and nonnew molecular entities and all related presubmissions, supplements, and amendments.

This guidance provides some general information on the organization and format of the CTD as well as recommendations for completing module 1, which contains administrative and prescribing information specific to each regulatory authority. The content of documents in the CTD is provided in other FDA guidance documents. When finalized, this guidance will supersede the "Guidelines on Formatting, Assembling, and Submitting of New Drug and Antibiotic Applications," issued in February 1987.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on general considerations for submitting marketing applications according to the ICH/CTD format. 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 (address above) written comments on the draft guidance. Two copies of any 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> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: August 28, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01-22199 Filed 9-4-01; 8:45 am]

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4650-N-64]

Notice of Submission of Proposed Information Collection to OMB; Pet Ownership in Public Housing for Elderly or Persons With Disabilities

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* October 5, 2001.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval number (2577-0078) and should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, Q, Department of Housing and Urban Development, 451 Seventh Street, Southwest, Washington, DC 20410; e-mail Wayne_Eddins@HUD.gov; telephone (202) 708-2374. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35). The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of

an information collection requirement; and (10) the name and telephone number of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

This Notice also lists the following information:

Title of Proposal: Pet Ownership in Public Housing for Elderly or Persons with Disabilities.

OMB Approval Number: 2577-0078.
Form Numbers: None.

Description of the Need for the Information and its Proposed Use:

• Public Housing Agencies (PHAs) give written notice to applicants that pets are permitted, working animals excluded from regulation requirements, and where leases prohibit pets, residents may request a lease

amendment. A copy of pet rules and written notice are given to each applicant when offered a unit.

Respondents: Individual or households, State, Local or Tribal Government.

Frequency of Submission: On occasion.

Reporting Burden:

Number of respondents	×	Frequency of response	×	Hours per response	=	Burden hours
32,000		1		0.08		256

Total Estimated Burden Hours: 256.
Status: Reinstatement, with change.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: August 27, 2001.

Wayne Eddins,

*Departmental Reports Management Officer,
Office of the Chief Information Officer.*

[FR Doc. 01-22171 Filed 9-4-01; 8:45 am]

BILLING CODE 4210-72-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[(OR-958-6320-ET; HAG01-0116; (OR-20221A))]

Public Land Order No. 7497; Partial Revocation of Executive Order Dated February 25, 1919; Oregon

AGENCY: Bureau of Land Management, Interior.

ACTION: Public land order.

SUMMARY: This order partially revokes an Executive Order insofar as it affects 240 acres of lands withdrawn for Bureau of Land Management Public Water Reserve No. 61. This revocation is in aid of the exchange legislated by the Steens Mountain Cooperative Management and Protection Act of 2000, Public Law 106-399. The lands have been open to metalliferous mining and mineral leasing under the terms of the withdrawal, but are temporarily closed to surface entry and all mining due to the pending legislated land exchange.

EFFECTIVE DATE: September 5, 2001.

FOR FURTHER INFORMATION CONTACT: Allison O'Brien, BLM Oregon/ Washington State Office, P.O. Box 2965, Portland, Oregon 97208-2965, 503-952-6171.

SUPPLEMENTARY INFORMATION: By virtue of the authority vested in the Secretary of the Interior by Section 204 of the Federal Land Policy and Management

Act of 1976, 43 U.S.C. 1714 (1994), it is ordered as follows:

1. The Executive Order dated February 25, 1919, which established Public Water Reserve No. 61, is hereby revoked insofar as it affects the following described lands:

Willamette Meridian

- T. 35 S., R. 32 3/4 E.,
Sec. 9, NW 1/4 SW 1/4;
- Sec. 17, SW 1/4 SW 1/4;
- Sec. 18, S 1/2 SE 1/4;
- Sec. 20, NE 1/4 NW 1/4;
- Sec. 28, NE 1/4 NW 1/4.

The areas described aggregate 240 acres in Harney County.

2. The above-described lands are hereby made available for exchange under Section 206 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1716 (1994).

Dated: August 15, 2001.

J. Steven Griles,

Deputy Secretary.

[FR Doc. 01-22180 Filed 9-4-01; 8:45 am]

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INTERNATIONAL TRADE COMMISSION

[Investigation No. 731-TA-894 (Final)]

Certain Ammonium Nitrate From Ukraine

Determination

On the basis of the record ¹ developed in the subject investigation, the United States International Trade Commission determines, pursuant to section 735(b) of the Tariff Act of 1930 (19 U.S.C. 1673d(b)) (the Act), that an industry in the United States is materially injured by reason of imports of certain ammonium nitrate from Ukraine, provided for in subheading 3102.30.00 of the Harmonized Tariff Schedule of

the United States, that have been found by the Department of Commerce to be sold in the United States at less than fair value (LTFV). The Commission further determines that critical circumstances do not exist with regard to those imports of the subject merchandise from Ukraine that were subject to the affirmative critical circumstances determination by the Department of Commerce.

Background

The Commission instituted this investigation on October 13, 2000, following receipt of a petition filed with the Commission and the Department of Commerce by counsel for the ad hoc Committee for Fair Ammonium Nitrate Trade ("COFANT"), including Air Products & Chemicals, Inc., Allentown, PA; El Dorado Chemical Co., Oklahoma City, OK; LaRoche Industries, Inc., Atlanta, GA; Mississippi Chemical Corp., Yazoo City, MS; and Nitram, Inc., Tampa, FL. The final phase of the investigation was scheduled by the Commission following notification of a preliminary determination by the Department of Commerce that imports of certain ammonium nitrate from Ukraine were being sold at LTFV within the meaning of section 733(b) of the Act (19 U.S.C. 1673b(b)). Notice of the scheduling of the Commission's investigation and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of March 14, 2001 (66 FR 14933). The hearing was held in Washington, DC on July 24, 2001, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission transmitted its determinations in this investigation to the Secretary of Commerce on August 31, 2001. The views of the Commission are contained in USITC Publication 3448, August 2001, entitled Certain

¹The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).