

FEDERAL MARITIME COMMISSION**Ocean Transportation Intermediary License; Rescission of Order of Revocation**

Notice is hereby given that the Order revoking the following license is being rescinded by the Federal Maritime Commission pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. Chapter 409) and the regulations of the Commission pertaining to the licensing of Ocean Transportation Intermediaries, 46 CFR part 515.

License Number: 019597N.

Name: United Cargo International, Inc.

Address: 30998 Huntwood Ave., #106 Hayward, CA 94544.

Order Published: FR: 07/29/09 (Volume 74, No. 144, Pg. 37711).

Sandra L. Kusumoto,

Director, Bureau of Certification and Licensing.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2009-N-0372]

Agency Information Collection Activities; Proposed Collection; Comment Request; Environmental Impact Considerations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection contained in FDA regulations entitled "Environmental Impact Considerations."

DATES: Submit written or electronic comments on the collection of information by November 9, 2009.

ADDRESSES: Submit electronic comments on the collection of information to [http://](http://www.regulations.gov)

www.regulations.gov. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Elizabeth Berbakos, Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3792.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Environmental Impact Considerations—21 CFR Part 25 (OMB Control Number 0910-0322)—Extension

FDA is requesting OMB approval for the reporting requirements contained in the FDA regulation "Environmental Impact Considerations." The National Environmental Policy Act (NEPA) (42

U.S.C. 4321-4347) states national environmental objectives and imposes upon each Federal agency the duty to consider the environmental effects of its actions. Section 102(2)(C) of NEPA requires the preparation of an environmental impact statement (EIS) for every major Federal action that will significantly affect the quality of the human environment. The FDA NEPA regulations are in part 25 (21 CFR part 25). All applications or petitions requesting agency action require the submission of a claim for a categorical exclusion or an environmental assessment (EA). A categorical exclusion applies to certain classes of FDA-regulated actions that usually have little or no potential to cause significant environmental effects and are excluded from the requirements to prepare an EA or EIS. Section 25.15(a) and (d) specifies the procedures for submitting to FDA a claim for a categorical exclusion. Extraordinary circumstances (§ 25.21), which may result in significant environmental impacts, may exist for some actions that are usually categorically excluded. An EA provides information that is used to determine whether an FDA action could result in a significant environmental impact. Section 25.40(a) and (c) specifies the content requirements for EAs for nonexcluded actions.

This collection of information is used by FDA to assess the environmental impact of agency actions and to ensure that the public is informed of environmental analyses. Firms wishing to manufacture and market substances regulated under statutes for which FDA is responsible must, in most instances, submit applications requesting approval. Environmental information must be included in such applications for the purpose of determining whether the proposed action may have a significant impact on the environment. Where significant adverse effects cannot be avoided, the agency uses the submitted information as the basis for preparing and circulating to the public an EIS, made available through a **Federal Register** document also filed for comment at the Environmental Protection Agency. The final EIS, including the comments received, is reviewed by the agency to weigh environmental costs and benefits in determining whether to pursue the proposed action or some alternative that would reduce expected environmental impact.

Any final EIS would contain additional information gathered by the agency's after the publication of the draft EIS, a copy of or a summary of the comments received on the draft EIS, and