

Column". This document corrects those errors.

#### **PART 774—[CORRECTED]**

■ In rule FR Doc. 04-7005, published on March 30, 2004 (69 FR 16478), make the following corrections. On page 16480, the middle column, correct the note to Export Control Classification Number 0A018, paragraph .c to read as follows:

**Note:** 0A018.c does not control weapons used for hunting or sporting purposes that were not specifically designed for hunting or sporting purposes that were not specially designed for military use and are not of the fully automatic type, but see 0A984 concerning shotguns.

■ On page 16480, the third column, in the Reason for Control paragraph of the License Requirements section of Export Control Classification Number 0E918, correct the third line in the Country Chart column to read: AT Column 1.

**Eileen Albanese,**

*Director, Office of Exporter Services.*

[FR Doc. 04-7808 Filed 4-5-04; 8:45 am]

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

#### **21 CFR Part 312**

##### **Emergency Use of an Investigational New Drug; Technical Amendment**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; technical amendment.

**SUMMARY:** The Food and Drug Administration (FDA) is amending its regulations to reflect a change in address for the agency contacts for submitting an investigational new drug application (IND) in an emergency situation. This action is editorial in nature and is intended to improve the accuracy of the agency's regulations.

**DATES:** This rule is effective April 6, 2004.

**FOR FURTHER INFORMATION CONTACT:**

Mark I. Fow, Office of Emergency Operations (HFA-615), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1240.

**SUPPLEMENTARY INFORMATION:** FDA is amending its regulations in part 312 (21 CFR part 312) to reflect a change in address for the agency contacts for submitting an IND in an emergency situation that does not allow time for submission of an IND in accordance

with § 312.23 or § 312.34. The current address for submission of investigational biological drugs in an emergency situation is the "Division of Biological Investigational New Drugs (HFB-230), Center for Biologics Evaluation and Research, 8800 Rockville Pike, Bethesda, MD 20892, 301-443-4864." The new address for investigational biological drugs regulated by the Center for Biologics Evaluation and Research is "Office of Communication, Training and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, 301-827-2000." The current contact for submission of all other investigational drugs in an emergency situation is the "Document Management and Reporting Branch (HFD-53), Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4320." The new contact is the "Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, 301-827-4570." The current contact for submitting requests for the Center for Biologics Evaluation and Research or the Center for Drug Evaluation and Research regulated products after normal working hours, eastern standard time, in an emergency situation is "FDA Division of Emergency and Epidemiological Operations, 202-857-8400." The new contact is "FDA Office of Emergency Operations (HFA-615), 301-443-1240."

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). Notice and public procedure are unnecessary because FDA is merely correcting nonsubstantive errors.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

#### **List of Subjects in 21 CFR Part 312**

Drugs, Exports, Imports, Investigations, Labeling, Medical research, Reporting and recordkeeping requirements, Safety.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 312 is amended as follows:

#### **PART 312—INVESTIGATIONAL NEW DRUG APPLICATION**

■ 1. The authority citation for 21 CFR part 312 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 355, 371; 42 U.S.C. 262.

■ 2. Section 312.36 is revised to read as follows:

#### **§ 312.36 Emergency use of an investigational new drug (IND).**

Need for an investigational drug may arise in an emergency situation that does not allow time for submission of an IND in accordance with § 312.23 or § 312.34. In such a case, FDA may authorize shipment of the drug for a specified use in advance of submission of an IND. A request for such authorization may be transmitted to FDA by telephone or other rapid communication means. For investigational biological drugs regulated by the Center for Biologics Evaluation and Research, the request should be directed to the Office of Communication, Training and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, 301-827-2000. For all other investigational drugs, the request for authorization should be directed to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, 301-827-4570. After normal working hours, eastern standard time, the request should be directed to the FDA Office of Emergency Operations (HFA-615), 301-443-1240. Except in extraordinary circumstances, such authorization will be conditioned on the sponsor making an appropriate IND submission as soon as practicable after receiving the authorization.

Dated: March 31, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04-7734 Filed 4-5-04; 8:45 am]

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## **DEPARTMENT OF HOMELAND SECURITY**

### **Coast Guard**

#### **33 CFR Parts 101 and 104**

**[USCG-2004-17350]**

##### **Interpretation of International Voyage for Security Regulations**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of interpretation.

**SUMMARY:** The Coast Guard is issuing an interpretation of the term "international voyage" as it is used in our recently-issued maritime security regulations. This interpretation will assist U.S. flag vessels operating in the waters of a foreign country in determining whether they must comply with the new International Ship and Port Facility