

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 312

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Certifier R. UDESMA

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 [*insert date of publication in the Federal Register*].

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

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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: 3:31.04

March 31, 2004.

Jeffrey Shuren

Jeffrey Shuren,
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