1858–01, manufactured before April 1, 1991, with a serial number (S/N) equal to or less than 8188, or P/N 704A33–640–046 (E1T3023–01), or delivered in pairs under the P/N 365A31–1858–02, manufactured before April 1, 1991, with a S/N equal to or less than 3122, is installed, remove the frequency adapter and replace it with an airworthy frequency adapter.

Note 2: Eurocopter France AS 365 Service Bulletin No. 01.00.44, dated May 9, 1996, pertains to the subject of this AD.

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, FAA, Rotorcraft Directorate, Rotorcraft Standards Staff. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Rotorcraft Standards Staff.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Rotorcraft Standards Staff.

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the helicopter to a location where the requirements of this AD can be accomplished.

(e) This amendment becomes effective on April 13, 1999.

Note 4: The subject of this AD is addressed in Direction General De L'Aviation Civile (France) AD 96–117–040(B), dated June 19, 1996.

Issued in Fort Worth, Texas, on March 1, 1999.

Eric Bries,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 99–5726 Filed 3–8–99; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 133

[T.D. 99–24]

Technical Amendment to the Customs Regulations

AGENCY: U.S. Customs Service, Department of the Treasury.

ACTION: Final rule.

SUMMARY: This document makes a minor technical change to the Customs Regulations, in accordance with Customs policy of periodically reviewing its regulations to make sure that they are current, and to eliminate needless repetition.

EFFECTIVE DATE: March 9, 1999.

FOR FURTHER INFORMATION CONTACT: Russell Berger, Office of Regulations and Rulings, 202–927–1605.

SUPPLEMENTARY INFORMATION:

Background

The general and specific sectional authority citations for part 133, Customs Regulations (19 CFR part 133), are set forth at the beginning of the part following its table of contents.

However, the specific statutory authority citations for certain sections in part 133 are also repeated immediately following the text of the sections.

Also, it is observed that 31 U.S.C. 483a is cited as authority for a number of sections in part 133 following the text of such sections. However, by Pub. L. 97–258 (September 13, 1982), 31 U.S.C. 483a was revised and replaced with 31 U.S.C. 9701 which is included under the general authority citation for part 133.

Accordingly, to eliminate unnecessary repetition and to make sure that the statutory authority listed for part 133 is correct and current, the statutory citations that appear in parentheses below the text of any regulatory sections in subparts A, B, D, E and F of part 133 will be deleted. It is noted that a document amending subpart C of part 133 that was published in the **Federal Register** (64 FR 9058) on February 24, 1999, as T.D. 99–21, effective as of March 26, 1999, no longer sets forth any statutory authority citations following the text of the regulatory sections in that subpart.

Inapplicability of Public Notice and Comment and Delayed Effective Date Requirements, the Regulatory Flexibility Act and Executive Order 12866

Because this amendment is merely of a minor editorial nature, and conforms to existing law, notice and public procedure in this case are inapplicable and unnecessary pursuant to 5 U.S.C. 553(b)(B), and pursuant to 5 U.S.C. 553(d)(3), a delayed effective date is not required. Since this document is not subject to the requirements of 5 U.S.C. 553, it is not subject to the provision of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Nor does the amendment result in a ''significant regulatory action'' under E.O. 12866.

List of Subjects in 19 CFR Part 133

Copyright, Customs duties and inspection, Fees assessment, Imports, Penalties, Prohibited merchandise, Reporting and recordkeeping requirements, Restricted merchandise (counterfeit goods), Seizures and forfeitures, Trade names, Trademarks, Unfair competition.

Amendment to the Regulations

Part 133, Customs Regulations (19 CFR part 133), is amended as set forth below.

PART 133—TRADEMARKS, TRADE NAMES, AND COPYRIGHTS

1. The authority citation for part 133 continues to read in part as follows:

Authority: 17 U.S.C. 101, 601, 602, 603; 19 U.S.C. 66, 1624; 31 U.S.C. 9701.

* * * * *

2. Part 133 is amended by removing the statutory authority citations that appear in parentheses immediately below the texts of §§ 133.1, 133.2–133.7, 133.11–133.13, 133.15, 133.33, 133.35, 133.36, 133.46, and 133.53.

Dated: March 3, 1999.

Harold M. Singer,

Chief, Regulations Branch.

[FR Doc. 99–5715 Filed 3–8–99; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 26

[Docket No. 98S–1064]

Implementation of the Mutual Recognition Agreement Between the United States and the European Community; Pharmaceutical GMP's and Medical Devices; Establishment of a Public Docket and FDA Contact Points

AGENCY: Food and Drug Administration, HHS.

ACTION: Establishment of a public docket and FDA contact points.

SUMMARY: The Food and Drug Administration (FDA) is announcing the establishment of a public docket for the submission and public availability of information concerning the implementation of the Mutual Recognition Agreement (MRA) between the United States and the European Community (EC) in the areas of pharmaceutical good manufacturing practices (GMP's) and medical devices. FDA is also establishing contact points for information covering particular subjects under the MRA implementation, and the agency is making appropriate information available on the FDA web site.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written comments to the Dockets Management Branch

(HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Documents concerning FDA's implementation of the MRA are available for public examination in the Dockets Management Branch.

FOR FURTHER INFORMATION CONTACT:

Pharmaceutical GMP's:

For information regarding human drug GMP's: Brian J. Hasselbalch, Division of Manufacturing and Product Quality (HFD–325), Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855–2737, 301–827–7285, FAX: 301–594–2202, or E-mail: ''hasselbalchb@cder.fda.gov''.

For information regarding animal drug GMP's: Judith A. Gushee, Office of Surveillance and Compliance (HFV–232), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855–2773, 301–827–0150, FAX: 301–594–1807, or E-mail: ''jgushee@bangate.fda.gov''.

For information regarding human biologic GMP's: Jennifer A. Thomas, Office of Compliance and Biologics Quality (HFM–600), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6190, FAX: 301–594–1944, or E-mail: ''thomasj@cber.fda.gov''.

Medical Devices:

For information regarding 510(k)'s: Eric J. Rechen, Office of Device Evaluation (HFZ–402), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186, FAX: 301–594–2977, or E-mail: ''ejr@cdrh.fda.gov''.

For information regarding device quality systems and GMP's: Kimberly A. Trautman, Office of Compliance (HFZ–340), Center for Devices and Radiological Health, Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4646, FAX: 301–594–4672, or E-mail: ''kat@cdrh.fda.gov''.

For information regarding third-party program administrative matters and general MRA issues: John F. Stigi, Division of Small Manufacturers Assistance (HFZ–220), Office of Health and Industry Programs, Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–7491, FAX: 301–443–8818, or E-mail: ''jfs@cdrh.fda.gov''.

SUPPLEMENTARY INFORMATION: On November 6, 1998, FDA published a final rule in the **Federal Register** (63 FR 60122) that amended its regulations under an international agreement between the United States and the EC by adding part 26 (21 CFR part 26), subparts A through C entitled ''Mutual Recognition of Pharmaceutical Good Manufacturing Practice Inspection Reports, Medical Device Quality System Audit Reports, and Certain Medical Device Product Evaluation Reports Between the United States and the European Community.'' This rule became effective on December 7, 1998. Under the terms of subpart A of part 26, the importing country authority may normally endorse pharmaceutical GMP inspection reports provided by exporting authorities determined to be equivalent. Under the terms of subpart B of part 26, the importing country authority may endorse quality system audits performed according to the importing country authority's requirements and procedures. In addition, certain medical device product evaluation reports performed by the exporting country's conformity assessment bodies (CAB's), according to the importing country authority's requirements and procedures, may normally be endorsed.

In response to comments on FDA's proposed rule published in the **Federal Register** of April 10, 1998 (63 FR 17744), FDA stated that it plans to make public summaries of key meetings held with its EC counterparts concerning implementation of the MRA and FDA's regulation, and that it will make available to the public the administrative file that constitutes the basis for any of FDA's equivalence determinations or listings, subject to exemptions from disclosure provided in the Freedom of Information Act, the Privacy Act, and FDA's regulations (see comment 1 in section II.C at 60122 at 60127).

Through this notice, FDA is establishing a new docket (Docket No. 98S–1064) in order to make available at a convenient location public information concerning the implementation of part 26.

Also, in the proposed rule (63 FR 17744), FDA requested (see also comment 1 in section II.C at 60122 at 60127) that all interested persons send to FDA information that is: (1) Generally relevant to implementation of part 26, and (2) of particular relevance to equivalence criteria described in part 26, Appendix D of subpart A and their application to authorities listed in Appendix B of subpart A of part 26. The notice instructed persons to send their information to docket 98N–0185 (the rulemaking docket).

FDA is particularly interested in obtaining the following types of information from any interested persons:

(a) Information relevant to determining the equivalence of EC Member State regulatory authorities that may provide pharmaceutical GMP inspection reports to FDA under the MRA, and

(b) Information relevant to the assessment procedures of CAB's that may provide medical device quality system evaluation reports and certain medical device product evaluation reports to the FDA under the MRA.

Because FDA desires to separate the administrative record of the rulemaking for part 26 from the administrative records covering implementation of part 26, FDA hereby requests that all information relevant to the implementation of part 26 be sent to the docket established under this notice (Docket No. 98S–1064). Furthermore, any information concerning implementation of part 26 and any information pertaining to the equivalence or listing criteria described previously that has already been sent to the rulemaking docket will be transferred to the new docket established for part 26 implementation.

FDA will also make appropriate information concerning the implementation of the MRA and part 26 available to the public on FDA's website at ''http://www.fda.gov'' under the ''International'' section.

Dated: March 2, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–5681 Filed 3–8–99; 8:45 am]

BILLING CODE 4160–01–F