FDC date	State	City	Airport	FDC No.	Subject
09/19/05	ID	Idaho Falls	Idaho Falls Regional	5/8505	NDB Rwy 20, Amdt 10B
09/19/05	ID	Idaho Falls	Idaho Falls Regional	5/8520	ILS Rwy 20, Amdt 11C
09/19/05	UT	Cedar City	Cedar City Regional	5/8521	ILS OR LOC Rwy 20, Amdt 3C
09/19/05	UT	Provo	Provo Muni	5/8522	ILS OR LOC/DME Rwy 13, Orig-A
09/19/05	UT	Roosevelt	Roosevelt Muni	5/8523	RNAV (GPS) Rwy 25, Orig-A
09/19/05	UT	Roosevelt	Roosevelt Muni	5/8524	VOR/DME RNAV Rwy 25, Amdt 2A
09/19/05	UT	Provo	Provo Muni	5/8526	VOR/DME Rwy 13, Amdt 1A
09/19/05	UT	Provo	Provo Muni	5/8527	VOR Rwy 13, Amdt 3A
09/19/05	UT	Moab	Canyon Lands Field	5/8528	VOR–A, Amdt 10A

[FR Doc. 05–19745 Filed 10–3–05; 8:45 am]
BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. 2005N–0341]

Medical Devices; Immunology and Microbiology Devices; Classification of AFP-L3% Immunological Test Systems

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying AFP-L3% (alpha-fetoprotein L3 subfraction) immunological test systems into class II (special controls). The special control that will apply to the device is the guidance document entitled ''Class II Special Controls Guidance Document: AFP-L3% Immunological Test Systems.'' The agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a guidance document that will serve as the special control for the device.

DATES: This rule is effective November 3, 2005. The classification was effective May 19, 2005.

FOR FURTHER INFORMATION CONTACT: Maria Chan, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0496.

SUPPLEMENTARY INFORMATION:

I. What is the Background of this Rulemaking?

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of FDA's regulations.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification (section 513(f)(2) of the act).

In accordance with section 513(f)(1) of the act, FDA issued an order on April 1, 2005, classifying the Wako LBA (liquid-phase binding assay) AFP-L3 in class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device that was subsequently reclassified into class I or class II. On April 6, 2005, Wako Chemical USA, Inc., submitted a petition requesting classification of the Wako AFP-L3 Test System under section 513(f)(2) of the act. The manufacturer recommended that the device be classified into class II.

In accordance with 513(f)(2) of the act, FDA reviewed the petition in order to classify the device under the criteria for classification set forth in 513(a)(1) of the act. Devices are to be classified into class II if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the petition, FDA determined that the Wako LBA AFP-L3 Test System can be classified into class II with the establishment of special controls. FDA believes these special controls will provide reasonable assurance of the safety and effectiveness of the device.

The device is assigned the generic name AFP-L3% immunological test system and it is identified as an in vitro device that consists of reagents and an automated instrument used to quantitatively measure, by immunochemical techniques, AFP and AFP-L3 subfraction in human serum. The device is intended for in vitro diagnostic use as an aid in the risk assessment of patients with chronic liver disease for development of hepatocellular carcinoma, in conjunction with other laboratory findings, imaging studies, and clinical assessment.

FDA has identified the risks to health associated with this type of device as inappropriate risk assessment and improper patient management. Failure of the system to perform as indicated, or error in interpretation of results, could lead to inappropriate risk assessment and improper management of patients with chronic liver diseases. Specifically, a falsely low AFP-L3% could result in a determination that the patient is at a lower risk of developing hepatocellular carcinoma, which could delay appropriate monitoring and treatment. A falsely high AFP-L3% could result in a determination that the patient is at a

higher risk for hepatocellular carcinoma, which could lead to unnecessary evaluation and testing, or inappropriate treatment decisions. Use of assay results without consideration of other laboratory findings, imaging studies, and clinical assessment could also pose a risk.

The class II special controls guidance document aids in mitigating potential risks by providing recommendations on validation of performance characteristics, including software validation, control methods, reproducibility, and clinical studies. The guidance document also provides information on how to meet premarket (510(k)) submission requirements for the device. FDA believes that following the recommendations in the class II special controls guidance document generally addresses the risks to health identified in the previous paragraph.

Following the effective date of this final classification rule, any firm submitting a 510(k) premarket notification for an AFP-L3% immunological test system will need to address the issues covered in the special controls guidance. However, the firm need only show that its device meets the recommendations of the guidance, or in some other way provides equivalent assurance of safety and effectiveness.

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under 510(k) of the act if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device and, therefore, the type of device is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the AFP-L3% immunological test system they intend to market.

II. What is the Environmental Impact of This Rule?

The agency has determined under 21 CFR 25.34(b) that this action is of type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. What is the Economic Impact of This Rule?

FDA has examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is not a significant regulatory action as defined by the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because classification of this device into class II will relieve manufacturers of the device of the cost of complying with the premarket approval requirements of section 515 of the act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202 (a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $115 million, using the most current (2003) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

IV. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

V. How Does This Rule Comply with the Paperwork Reduction Act of 1995?

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3502) is not required.

FDA also tentatively concludes that the special controls guidance document identified by this rule contains information collection provisions that are subject to review and clearance by OMB under the PRA. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing the availability of the draft guidance document entitled ''Class II Special Controls Guidance Document: AFP-L3% Immunological Test Systems.''

VI. What References Are on Display?

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from Wako Chemical USA, Inc., received April 7, 2005.

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for 21 CFR part 866 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Section 866.6030 is added to subpart G to read as follows:

§ 866.6030 AFP-L3% immunological test system.

(a) *Identification.* An AFP-L3% immunological test system is an in vitro device that consists of reagents and an automated instrument used to quantitatively measure, by immunochemical techniques, AFP and AFP-L3 subfraction in human serum. The device is intended for in vitro

diagnostic use as an aid in the risk assessment of patients with chronic liver disease for development of hepatocellular carcinoma, in conjunction with other laboratory findings, imaging studies, and clinical assessment.

(b) *Classification.* Class II (special controls). The special control is FDA's guidance document entitled ''Class II Special Controls Guidance Document: AFP-L3% Immunological Test Systems.'' See § 866.1(e) for the availability of this guidance document.

Dated: September 9, 2005.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 05–19863 Filed 10–3–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9223]

RIN 1545–BC20

Value of Life Insurance Contracts When Distributed From a Qualified Retirement Plan; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to final regulations.

SUMMARY: This document contains a correction to final regulations that were published in the **Federal Register** on Monday, August 29, 2005 (70 FR 50967) regarding the amount includible in a distributee's income when life insurance contracts are distributed by a qualified retirement plan and regarding the treatment of property sold by a qualified retirement plan to a plan participant or beneficiary for less than fair market value.

FOR FURTHER INFORMATION CONTACT: Concerning the section 79 regulations, Betty Clary at (202) 622–6080; concerning the section 83 regulations, Robert Misner at (202) 622–6030; concerning the section 402 regulations, Bruce Perlin or Linda Marshall at (202) 622–6090 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 9223) that are the subject of this correction are under sections 402(a), 79 and 83 of the Internal Revenue Code.

Need for Correction

As published, TD 9223 contains an error that may prove to be misleading and is in need of clarification.

Correction of Publication

Accordingly, the publication of the final regulations (TD 9223) which was the subject of FR Doc. 05–17046, is corrected as follows:

On page 50969, column 2, in the preamble, under the paragraph heading ''*B. The 2004 Proposed Regulations*'', line 2 from the top of the column, the language ''§ 1.79-(d) to replace the term ''cash'' is corrected read ''§ 1.79–1(d) to replace the term ''cash''.

Cynthia Grigsby,

Acting Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

[FR Doc. 05–19776 Filed 10–3–05; 8:45 am]

BILLING CODE 4830–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[R04–OAR–2004–KY–0003–200529; FRL–7979–7A]

Approval and Promulgation of Implementation Plans for Kentucky: Inspection and Maintenance Program Removal for Northern Kentucky; New Solvent Metal Cleaning Equipment; Commercial Motor Vehicle and Mobile Equipment Refinishing Operations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is approving four related revisions to the Kentucky State Implementation Plan (SIP) submitted by the Commonwealth of Kentucky on February 9, 2005. These revisions affect the Northern Kentucky area, which is comprised of the Kentucky Counties of Boone, Campbell, and Kenton, and is part of the Cincinnati-Hamilton Metropolitan Statistical Area. EPA is approving the movement of the regulation underlying the Northern Kentucky inspection and maintenance (I/M) program from the regulatory portion of the Kentucky SIP to the contingency measures section of the Northern Kentucky 1-Hour Ozone Maintenance Plan. EPA is also approving revisions to a Kentucky rule which provides for the control of volatile organic compounds (VOCs) from new solvent metal cleaning equipment. Further, EPA is approving a new rule into the Kentucky SIP affecting commercial motor vehicle and mobile equipment refinishing operations in Northern Kentucky. Finally, EPA is approving updated mobile source category emissions projections with updated, state motor vehicle emission budgets (MVEBs) for the year 2010. This final rule addresses comments made on EPA's proposed rulemaking previously published for this action.

EFFECTIVE DATE: This rule will be effective November 3, 2005.

ADDRESSES: EPA has established a docket for this action under Regional Material in EDocket (RME) ID No. R04–OAR–2004–KY–0003. All documents in the docket are listed in the RME index at *http://docket.epa.gov/rmepub/.* Once in the system, select ''quick search,'' then key in the appropriate RME Docket identification number. Although listed in the index, some information is not publicly available, i.e., Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in RME or in hard copy at the Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the contact listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding federal holidays.

FOR FURTHER INFORMATION CONTACT: Michele Notarianni, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, Region 4, U.S. Environmental Protection Agency, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960. Ms. Notarianni can be reached via telephone number at (404) 562–9031 or electronic mail at *notarianni.michele@epa.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents