Orders 7400.2E and 8260.19C. This area will be depicted on appropriate aeronautical charts. Class E airspace areas extending upward from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9L, Airspace Designations and Reporting Points, dated September 2, 2003, and effective September 16, 2003, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

The Direct Final Rule Procedure

The FAA anticipates that this regulation will not result in adverse or negative comment and, therefore, is issuing it as a direct final rule. Previous actions of this nature have not been controversial and have not resulted in adverse comments or objections. Unless a written adverse or negative comment, or a written notice of intent to submit an adverse or negative comment is received within the comment period, the regulation will become effective on the date specified above. After the close of the comment period, the FAA will publish a document in the **Federal Register** indicating that no adverse or negative comments were received and confirming the date on which the final rule will become effective. If the FAA does receive, within the comment period, an adverse or negative comment, or written notice of intent to submit such a comment, a document withdrawing the direct final rule will be published in the **Federal Register**, and a notice of proposed rulemaking may be published with a new comment period.

Comments Invited

Interested parties are invited to participate in this rulemaking by submitting such written date, views, or arguments, as they may desire. comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2004–17425/Airspace Docket No. 04–ACE–25.'' The postcard will be date/time stamped and returned to the commenter.

Agency Findings

The regulations adopted herein will not have a substantial direct effect 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. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

The FAA has determined that this regulation is noncontroversial and unlikely to result in adverse or negative comments. For the reasons discussed in the preamble, I certify that this regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

■ Accordingly, the Federal Aviation Administration amends 14 CFR Part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9L, dated September 2, 2003, and effective September 16, 2003, is amended as follows:

* * * * *

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ACE NE E5 Holdrege, NE

Holdrege, Brewster Field, NE

(Lat. 40°27′10″ N., long. 99°20′14″ W).
Holdrege NDB

(Lat. 40°26′53″ N., long. 99°20′27″ W.)
Kearney VOR

(lat. 40°43′32″ N., long. 99°00′18″ W.)

That airspace extending upward from 700 feet above the surface within a 6.6-mile radius of Brewster Field and within 2.6 miles each side of the 014° bearing from the Holdrege NDB extending from the 6.6-mile radius of the airport to 7 miles north of the NDB and within 2.6 miles each side of the Kearney VOR 222° radial extending from the 6.6-mile radius to 11 miles northeast of the airport.

* * * * *

Issued in Kansas City, MO, on April 27, 2004.

Paul J. Sheridan,

Acting Manager, Air Traffic Division, Central Region.

[FR Doc. 04–10641 Filed 5–10–04; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. 2004P–0126]

Medical Devices; Immunology and Microbiology Devices; Classification of the Immunomagnetic Circulating Cancer Cell Selection and Enumeration System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the Immunomagnetic Circulating Cancer Cell Selection and Enumeration System device 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: Immunomagnetic Circulating Cancer Cell Selection and Enumeration System.'' The agency is taking this action in response to a petition submitted under the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Medical Device Amendments of 1976 (the amendments), the Safe Medical Devices Act of 1990 (the SMDA), the Food and Drug Administration Modernization Act of 1997 (FDAMA), and the Medical Device User Fee and Modernization Act of 2002 (MDUFMA). 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 publishing a notice of availability of a guidance document that is the special control for this device.

DATES: This rule is effective June 10, 2004. The classification was effective January 21, 2004.

FOR FURTHER INFORMATION CONTACT: Nina Chace, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1293, ext. 138.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of 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 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 previously marketed 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 (513(f)(2) of the act).

In accordance with section 513(f)(1) of the act, FDA issued a notice on December 24, 2003, classifying the CellSearch Epithelial Cell Kit/Cell Spotter Analyzer 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 which was subsequently reclassified into class I or class II. On December 24, 2003, Veridex, LLC, submitted a petition requesting classification of the CellSearch Epithelial Cell Kit/Cell Spotter Analyzer under section 513(f)(2) of the act. The manufacturer recommended that the device be classified into class II (Ref. 1).

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 CellSearch Epithelial Cell Kit/Cell Spotter Analyzer can be classified in class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of safety and effectiveness of the device.

The device is assigned the generic name immunomagnetic circulating cancer cell selection and enumeration system and is identified as a device consisting of biological probes, fluorochromes, and other reagents; preservation and preparation devices; and a semiautomated analytical instrument to select and count circulating cancer cells in a prepared sample of whole blood. This device is intended for adjunctive use in monitoring or predicting cancer disease progression, response to therapy, and for the detection of recurrent disease.

FDA has identified no direct risks to health when tests are used as an aid to monitoring and predicting cancer disease progression and response to therapy. However, failure of the test to perform as indicated, or an error in interpretation of results, could lead to misdiagnosis and improper treatment, improper patient management, improper treatment selection and dosing, and failure to identify circulating cancer cells. Consequently, FDA has identified the following risks to health associated with this type of device: (1) False negative, false low cancer cell count; and (2) false positive, false high cancer cell count. Therefore, in addition to the general controls of the act, the device is subject to special controls, identified as the guidance document entitled ''Class II Special Controls Guidance Document: Immunomagnetic Circulating Cancer Cell Selection and Enumeration System.''

The class II special controls guidance document provides information on how to meet premarket (510(k)) submission requirements for the device including recommendations on validation of performance characteristics, including software validation; control methods; reproducibility; and clinical studies. FDA believes that following the class II special controls guidance document addresses the risks to health identified in the previous paragraph. Therefore, on January 21, 2004, FDA issued an order to the petitioner classifying the device into class II. FDA is codifying this classification by adding 21 CFR 866.6020.

Following the effective date of this final classification rule, any firm submitting a 510(k) premarket notification for an immunomagnetic circulating cancer cell selection and enumeration 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 section 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 safety and effectiveness; therefore, the device is not exempt from premarket notification requirements. The device is used as an adjunct in monitoring or predicting cancer disease progression and response to therapy and for detection of recurrent disease. FDA's review of the test's sensitivity, specificity, and reproducibility with regard to key performance characteristics, test methodology and other relevant performance data, will ensure that acceptable levels of performance for both safety and effectiveness will be addressed before marketing clearance. Thus, 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 immunomagnetic circulating cancer cell selection and enumeration system they intend to market.

II. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this action is of a 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. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and 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 consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the final rule is not a significant regulatory action as defined by the Executive order and so it is not subject to review under 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. Classification of these devices 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, therefore, certifies that the final rule will not have a significant impact on a substantial number of small entities. In addition, this final rule will not impose costs of $100 million or more on either the private sector or State, local, and tribal governments in the aggregate and, therefore, a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act is not required.

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. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VI. Reference

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 Veridex, LLC, dated December 24, 2003.

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 866.6020 is added to subpart G to read as follows:

§ 866.6020 Immunomagnetic circulating cancer cell selection and enumeration system.

(a) *Identification.* An immunomagnetic circulating cancer cell selection and enumeration system is a device that consists of biological probes, fluorochromes, and other reagents; preservation and preparation devices; and a semiautomated analytical instrument to select and count circulating cancer cells in a prepared sample of whole blood. This device is intended for adjunctive use in monitoring or predicting cancer disease progression, response to therapy, and for the detection of recurrent disease.

(b) *Classification.* Class II (special controls). The special control for this device is FDA's guidance document entitled ''Class II Special Controls Guidance Document: Immunomagnetic Circulating Cancer Cell Selection and Enumeration System.'' See § 866.1(e) for availability of this guidance document.

Dated: April 26, 2004.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 04–10592 Filed 5–10–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9127]

RIN 1545–BC47

Reduction of Tax Attributes Due to Discharge of Indebtedness

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains final regulations regarding the reduction of tax attributes under sections 108 and 1017 of the Internal Revenue Code. These final regulations affect taxpayers that realize income from the discharge of indebtedness that is excluded from gross income pursuant to section 108.

DATES: *Effective Date:* These final regulations are effective May 10, 2004.

Applicability Date: These final regulations apply to discharges of indebtedness occurring on or after May 10, 2004.

FOR FURTHER INFORMATION CONTACT: Theresa M. Kolish (202–622–7530) of the Office of Associate Chief Counsel (Corporate) (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background and Explanation of Provisions

On July 18, 2003, the IRS and Treasury Department promulgated temporary regulations providing guidance regarding the application of the attribute reduction rules of sections 108 and 1017. Those temporary regulations clarified that, in the case of a transaction described in section 381(a) that ends a year in which the distributor or transferor corporation excludes income from the discharge of indebtedness from gross income under section 108(a)(excluded COD income), any tax attributes to which the acquiring corporation succeeds, including the basis of property acquired by the acquiring corporation in the transaction, must reflect the reductions required by