4. The provisions of the Administrative Procedure Act requiring notice of proposed rulemaking, the opportunity for public participation, and a delay in effective date, are inapplicable because this regulation involves a military or foreign affairs function of the United States (see 5 U.S.C. 553(a)(1)). Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, are inapplicable.

Therefore, this regulation is issued in final form. Although there is no formal comment period, public comments on this regulation are welcome on a continuing basis. Comments should be submitted to Sharron Cook, Office of Exporter Services, Bureau of Export Administration, Department of Commerce, PO Box 273, Washington, DC 20044.

List of Subjects in 15 CFR Part 744

Exports, Foreign trade, Reporting and recordkeeping requirements.

Accordingly, part 744 of the Export Administration Regulations (15 CFR parts 730–744) is amended, as follows:

PART 744—[AMENDED]

1. The authority citation for 15 CFR part 744 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*, 1701 *et seq.;* 22 U.S.C. 3201 *et seq.;* 42 U.S.C. 2139a; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12924, 59 FR 43437, 3 CFR, 1994 Comp., p. 917; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; Notice of August 15, 1995 (60 FR 42767, August 17, 1995); and Notice of August 14, 1996 (61 FR 42527); and August 13, 1997 (62 FR 43629, August 15, 1997).

2. Part 744 is amended by adding a new § 744.10 to read as follows:

§ 744.10 Restrictions on certain entities in Russia.

(a) *General prohibition.* Certain entities in Russia, under investigation by the Russian government for suspected export control violations involving weapons of mass destruction and missile technology, are included in Supplement No. 4 of this part 744 (Entity List). (See also § 744.1(c) of the EAR.) Exporters are hereby informed that these entities are ineligible to receive any items subject to he EAR without a license.

(b) *Exceptions.* No License Exceptions apply to the prohibition described in paragraph (a) of this section.

(c) *License review standards.* Applications to export or reexport items subject to the EAR to these entities will be reviewed with a presumption of denial.

3. Supplement No. 4 to part 744 is amended by adding, in alphabetical order, the following entities:

Supplement No. 4 to part 744—Entity List

* * * * *

Baltic State Technical University, 1/21, 1-ya Krasnoarmeiskaya UI., 198005 St. Petersburg, Russia, for all items subject to the EAR (see § 744.10 of the EAR)

* * * * *

Europalace 2000, Moscow, Russia, for all items subject to the EAR (see § 744.10 of the EAR)

Glavkosmos, 9 Krasnoproletarskaya st., 103030 Moscow, Russia, for all items subject to the EAR (see § 744.10 of the EAR)

Garfit (aka State Scientific Research Institute of Graphite or NIIGRAFIT), 2 Ulitsa Elektrodnaya, 111524 Moscow, Russia, for all items subject to the EAR (see § 744.10 of the EAR)

* * * * *

INOR Scientific Center, Moscow, Russia, for all items subject to the EAR (see § 744.10 of the EAR)

* * * * *

MOSO Company, Moscow, Russia, for all items subject to the EAR (see § 744.10 of the EAR)

* * * * *

Polyus Scientific Production Association, 3 Ulitsa Vvedenskogo, 117342 Moscow, Russia, for all items subject to the EAR (see § 744.10 of the EAR)

* * * * *

Dated: July 23, 1998.

R. Roger Majak,

Assistant Secretary for Export Administration.

[FR Doc. 98–20272 Filed 7–28–98; 8:45 am]

BILLING CODE 3510–33–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 862

[Docket No. 96P–0228]

Medical Devices; Reclassification and Codification of Vitamin D Test System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it has issued an order in the form of a letter to INCSTAR Corp. reclassifying INCSTAR 25–Hydroxyvitamin D ^{125}I Radioimmunoassay (RIA). This radioimmunoassay device is intended for use in clinical laboratories for the quantitative determination of 25-hydroxyvitamin D (25–OH–D) and other hydroxylated metabolites of vitamin D in serum or plasma to be used in the assessment of vitamin D sufficiency. The device and substantially equivalent devices of this generic type were reclassified from class III (premarket approval) to class II (special controls). Accordingly, the order is being codified in the Code of Federal Regulations.

EFFECTIVE DATES: The regulation is effective August 28, 1998. The reclassification was effective September 24, 1996.

FOR FURTHER INFORMATION CONTACT: Sharon K. Lappalainen, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1243.

SUPPLEMENTARY INFORMATION:

I. Background (Regulatory Authorities)

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295), the Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101–629), and the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation

classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until: (1) The device is reclassified into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with new section 513(f)(2) of the act as amended by FDAMA; or (3) FDA issues an order finding the device to be substantially equivalent, under 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 offered 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 the regulations.

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Reclassification of postamendments devices is governed by section 513(f)(3) of the act, formerly section 513(f)(2) of the act. This section provides that FDA may initiate the reclassification of a device classified into class III under section 513(f)(1) of the act, or the manufacturer or importer of a device may petition the Secretary of the Department of Health and Human Services (the Secretary) for the issuance of an order classifying the device in class I or class II. FDA's regulations in § 860.134 (21 CFR 860.134) set forth the procedures for the filing and review of a petition for reclassification of such class III devices. In order to change the classification of the device, it is necessary that the proposed new class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

FDAMA added paragraph (f)(2) in section 513 of the act that addresses classification of postamendments devices. New paragraph (f)(2) in section 513 of the act provides that upon receipt of a ''not substantially equivalent'' determination, a 510(k) applicant may request FDA to classify a postamendments device into class I or class II. Within 60 days from the date of such a written request, FDA must classify the device by written order. If FDA classifies the device into class I or II, the applicant has then received clearance to market the device and it can be used as a predicate device for other 510(k)'s. It is expected that this will be used for low risk devices. This process does not apply to devices that have been classified by regulation into class III—i.e., preamendments class III devices, or class III devices for which a PMA is appropriate.

Under section 513(f)(3)(B)(i) of the act, formerly section 513(f)(2)(B)(i) of the act, the Secretary may, for good cause shown, refer a petition to a device classification panel. If a petition is referred to a panel, the panel shall make a recommendation to the Secretary respecting approval or denial of the petition. Any such recommendation shall contain: (1) A summary of the reasons for the recommendation, (2) a summary of the data upon which the recommendation is based, and (3) an identification of the risks to health (if any) presented by the device with respect to which the petition was filed.

On July 1, 1996, FDA filed the reclassification petition submitted by INCSTAR Corp., requesting reclassification of the vitamin D test system from class III to class II.

On the basis of FDA's review of the data submitted in the reclassification petition, and after reviewing the panel's recommendations on two previous petitions submitted in 1983 and 1985 regarding the quantitative measurement of vitamin D, FDA issued an order to the petitioner, reclassifying vitamin D test system for use in clinical laboratories for the quantitative determination of 25–OH–D and other hydroxylated metabolites of vitamin D in serum or plasma to be used in the assessment of vitamin D sufficiency, and substantially equivalent devices of this generic type, from class III to class II. Accordingly, as required by § 860.134(b)(7) of the regulations, FDA is announcing the reclassification of the vitamin D test system intended for use in clinical laboratories for the quantitative determination of 25–OH–D and other hydroxylated metabolites of vitamin D in serum or plasma to be used in the assessment of vitamin D sufficiency from class III into class II. In addition, FDA is issuing the notice to codify the reclassification of the device by adding new § 862.1825.

II. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this reclassification 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 this final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354) (as amended by the subtitle D of the Small Business Regulatory Fairness Act of 1996 (Pub. L. 104–121)), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 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 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. Reclassification of this device from class III to class II will relieve all manufacturers of the device of the cost of complying with the premarket approval requirements of section 515 of the act. Because reclassification will reduce regulatory costs with respect to this device, it will impose no significant economic impact on any small entities, and it may permit small potential competitors to enter the marketplace by lowering their costs. The agency therefore certifies that this final rule will not have a significant economic 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 or analysis under section 202(a) of the Unfunded Mandates Refund Act of 1995 is not required.

IV. Paperwork Reduction Act of 1995

FDA has determined that 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.

List of Subjects in 21 CFR Part 862

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 862 is amended as follows:

PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

1. The authority citation for 21 CFR part 862 continues to read as follows:

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

2. Section 862.1825 is added to subpart B to read as follows:

§ 862.1825 Vitamin D test system.

(a) *Identification*. A vitamin D test system is a device intended for use in clinical laboratories for the quantitative determination of 25-hydroxyvitamin D (25–OH–D) and other hydroxylated metabolites of vitamin D in serum or plasma to be used in the assessment of vitamin D sufficiency.

(b) *Classification*. Class II (special controls).

Vitamin D test systems must comply with the following special controls: (1) Labeling in conformance with 21 CFR 809.10 and (2) compliance with existing standards of the National Committee on Clinical Laboratory Standards.

Dated: July 17, 1998.

D.B. Burlington.

Director, Center for Devices and Radiological Health.

[FR Doc. 98–20241 Filed 7–28–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8776]

RIN 1545–AW34

Conversion to the Euro

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains temporary Income Tax Regulations relating to U.S. taxpayers operating, investing or otherwise conducting business in the currencies of certain European countries that are replacing their national currencies with a single, multinational currency called the euro. These regulations provide rules relating to adjustments required for qualified business units operating in such currencies and rules relating to the tax effect of holding such currencies or financial instruments or contracts denominated in such currencies. The text of these temporary regulations also serves as the text of proposed regulations published elsewhere in this issue of the **Federal Register**.

DATES: These regulations are effective July 29, 1998.

FOR FURTHER INFORMATION CONTACT: Howard Wiener of the Office of Associate Chief Counsel (International), (202) 622–3870, regarding the change in functional currency rules and Thomas Preston of the Office of Assistant Chief Counsel (Financial Institutions and Products), (202) 622–3930, regarding section 1001 (not toll free calls).

SUPPLEMENTARY INFORMATION:

Background

On March 9, 1998, the IRS issued Announcement 98–18 (1998–9 IRB 44) requesting comments relating to the tax issues for U.S. taxpayers operating, investing or otherwise conducting business in a currency that is converting to the euro. Numerous comments were received. After consideration of these comments, these regulations are adopted as a temporary Treasury decision to provide immediate guidance to taxpayers.

Explanation of Provisions

I. Background

The Treaty on European Union signed February 7, 1992, (31 I.L.M. 247) (entered into force November 1, 1993), sets forth a plan to replace the national currencies of participating members (legacy currencies) that meet certain economic criteria with a single European currency (euro). Pursuant to directives of the European Council, the process of converting the legacy currencies into the euro will take place in three phases.

On January 1, 1999, the currency of participating member states of the European Union shall be the euro. At that time, the euro will be substituted for the currency of each state at a conversion rate established pursuant to the Treaty on European Union. Thereafter, the bills and coins of each of the legacy currencies will remain in circulation but will cease to have independent value apart from the euro. On January 1, 2002, euro bills and coins will be introduced into circulation. From January 1, 1999, until June 30, 2002 (transition period), the legacy currencies will remain in circulation as subunits of the euro. The transition period is referred to as the ''no prohibition, no compulsion'' period because during this time amounts may generally be denominated in the legacy currencies and/or the euro at the option of individuals and businesses. Finally, by July 1, 2002, the legacy currencies will no longer be accepted as legal tender.

On May 3, 1998, the European Union announced the eleven countries that would initially participate in the conversion and the expected rates at which the respective currencies would convert to the euro. The eleven countries are Austria, Belgium, Finland, France, Germany, Ireland, Italy, Luxembourg, Netherlands, Portugal, and Spain. Four current members of the European Union (Denmark, Greece, Sweden, and the United Kingdom) will not participate in the initial conversion to the euro. These countries, along with other countries that later join the European Union, however, may convert their currencies to the euro at some future time.

II. Temporary Regulations

1. In General

These temporary regulations provide guidance regarding certain of the federal income tax consequences arising from the introduction of the euro. Consistent with comments received from taxpayers, the regulations generally minimize the tax consequences that arise by reason of the euro conversion. In a limited number of circumstances, however, the Treasury and IRS determined that considerations, such as administrative feasibility, made a different result more appropriate.

The regulations provide guidance with respect to two issues: (i) the circumstances under which the euro conversion creates a realization event with respect to instruments and contracts denominated in a legacy currency, and (ii) the circumstances under which the euro conversion constitutes a change in functional currency for a qualified business unit (QBU) whose functional currency is a legacy currency, and certain consequences thereof.

2. Realization

The temporary regulations provide that the conversion of legacy currencies to the euro does not result in a realization event under section 1001. This rule is broadly applicable to all situations where the rights and obligations of a taxpayer are altered solely by reason of the euro conversion. Thus, conversion to the euro of legacy