Dated: December 16, 2004.

Peter Lichtenbaum,

Assistant Secretary for Export Administration.

[FR Doc. 04–28104 Filed 12–22–04; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 179

[Docket No. 2003F–0088]

Irradiation in the Production, Processing and Handling of Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations by establishing a new maximum permitted energy level of x rays for treating food of 7.5 million electron volts (MeV) provided that the x rays are generated from machine sources that use tantalum or gold as the target material, with no change in the maximum permitted dose levels or uses currently permitted by FDA's food additive regulations. This action is in response to a petition filed by Ion Beam Applications.

DATES: This rule is effective December 23, 2004. Submit written objections and request for a hearing by January 24, 2005. See Section VII of this document for information on the filing of objections.

ADDRESSES: You may submit written objections and requests for a hearing, identified by Docket No. 2003F–0088, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.
- E-mail: *fdadockets@oc.fda.gov*. Include Docket No. 2003F–0088 in the subject line of your e-mail message.
- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All objections received will be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For detailed instructions on submitting objections, see the ''Objections'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Celeste Johnston, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1282.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the **Federal Register** of March 13, 2003 (68 FR 12087), FDA announced that a food additive petition (FAP 3M4745) had been filed by Ion Beam Applications (IBA), 6000 Poplar Ave., suite 426, Memphis, TN. Since the publication of this notice, IBA has been sold to PPM Ventures, which subsequently changed its name to Sterigenics International, Inc., 2015 Spring Rd., suite 650, Oak Brook, IL 60523. As a result, the rights to FAP 3M4745 have been transferred from IBA to Sterigenics International, Inc. The petition proposed that the food additive regulations in § 179.26 *Ionizing radiation for the treatment of food* (21 CFR 179.26) be amended by increasing the maximum permitted energy level of x rays for treating food to 7.5 MeV from the currently permitted maximum level of 5 MeV. Higher x ray energy will result in an increased concentration of x rays in the forward direction and increased penetration of these x rays in materials. This increased emission efficiency (i.e., concentration of x rays produced in the forward direction) will result in reduced treatment time for food, and therefore, higher production rates and lower treatment costs. The increased penetration of 7.5 MeV versus 5 MeV x rays will allow for the irradiation of larger packages.

II. Evaluation of Safety

A source of radiation used to treat food meets the definition of a food additive under section 201(s) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(s)). Under section 409(c)(3)(A) of the act (21 U.S.C. 348(c)(3)(A)), a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. FDA's food additive regulations in 21 CFR 170.3(i) define safe as ''a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.''

III. Evaluation of the Safety of the Petitioned Use of 7.5 MeV X Rays

A. Safety Concerns of Higher Energy X rays

The maximum energy limit of an x-ray machine is the maximum energy of the individual x-ray photons produced by that machine. When individual photons of x rays are absorbed by food, the absorbed energy causes atoms to be ionized until all the energy is converted into heat or chemical change. The amount of change in the food will depend on the total energy absorbed (i.e., dose). Because this petition seeks only to raise the maximum energy limit for x rays used for treating food, with no change in the maximum doses currently permitted by § 179.26, FDA concludes that the petition presents no new chemical issue, and that the only safety issue to be addressed is the potential for inducing radioactivity in the food.

Food, as well as other natural materials, displays low levels of naturally occurring radioactivity, such as that due to the presence of potassium-40 or carbon-14. To assess the safety of increasing the maximum energy of x rays to 7.5 MeV, the petitioner evaluated the potential for 7.5 MeV x rays to induce additional radioactivity in food. X rays with energies above an atom's threshold energy are capable of ejecting neutrons or protons from the nuclei of some atoms that have absorbed the x-ray energy. The threshold energy needed to cause the emission of a proton is higher than 7.5 MeV; therefore, the primary mechanism for inducing radioactivity in food by 7.5 MeV x rays will be from the loss of a neutron. This may in some cases result in the formation of radioactive nuclei. Radioactive nuclei are unstable and decay to a more stable form, spontaneously emitting particles and electromagnetic radiation in the form of gamma rays (i.e., high-energy photons). Often, this transition can occur very rapidly, such that an isotope produced in food from x rays will decay to a stable, nonradioactive state before leaving the irradiation facility. However, some radioactive isotopes could be sufficiently stable to be present in food

when ingested. Radioactive atoms decay at a rate specific to their identity and, if taken into the body, could emit ionizing energy that would be absorbed in tissues in the body. Whether any emitted energy would increase the risk of harm to health depends on the amount and type of radiation absorbed by the body and the site of absorption.

Two reports in the petition provide the petitioner's primary basis that the petitioned use of 7.5 MeV x-ray radiation is safe. One report, from the International Atomic Energy Agency (IAEA), addresses natural and induced radioactivity in food treated with radiation, including high energy x rays (Ref. 1). The second report, by Gregoire et al., assesses the induced activities in fresh meat and in meat ash irradiated with high-energy x rays using evidence provided by theoretical calculations and experimental measurement (Ref. 2). As part of its review, FDA contracted with the Department of Energy, Oak Ridge National Laboratory (ORNL), for an independent evaluation of data in the petition (Ref. 3).

B. Neutron-Induced Radioactivity in Food

The IAEA report provides a compilation of available data on natural and induced radioactivity in food and investigates to what extent increases in absorbed dose in food or increased energy levels of radiation sources used to irradiate food could induce radioactivity in the food. One of the scenarios considered in the report was the potential for inducing radioactivity in food after being irradiated with 7.5 MeV x rays (using an x-ray target of tantalum or gold) to a dose of 30 kiloGray (kGy).[1] The report compared possible radiation exposure in humans from induced radioactivity in food to that from natural radioactivity in food. A reference food model was used for this analysis with an elemental composition similar to that of meat.[2] The report concluded that consuming 40 kilograms (kg) (88 pounds) per year of reference food with an absorbed dose of 30 kGy (a dose more than six times the maximum permitted dose level of 4.5 kGy permitted by FDA for refrigerated meat and meat products), would result in an estimated human radiation exposure of 1.3×10^{-3} millisieverts/year (yr) (mSv/yr) (a dose 300 times less than the yearly dose due to natural radioactivity from food) (Ref. 1). The calculation assumed that the food would be eaten immediately after being irradiated. However, the radioisotopes with the greatest probability of being produced decay quite rapidly. Therefore, because of radioactive decay, any radioactivity in the treated food, which would normally be consumed more than 24 hours after treatment, would actually be significantly less at the time of consumption.

The report by Gregoire et al. provided theoretical estimates and experimental results of the radiological implications of irradiating meat with higher energy x rays. Induced activities in meat irradiated at 15 kGy with 7.5 MeV x rays and a resultant human exposure to radiation were calculated. Based on the most abundant isotopes produced in meat by neutron capture reactions at thresholds below 7.5 MeV, and assuming a person consumes 40 kg of meat per year and a 24-hour delay between irradiation and consumption, the corresponding dose to humans was calculated to be 0.2×10^{-3} mSv/yr.

Theoretical estimates of induced activity can be more reliable than direct measurements, especially for low levels of activity. However, to check the validity of the theoretical estimates, Gregoire et al. compared their predictions with experimental data. Experimental results from a 1991 study by Wakeford and Blackburn were discussed. This study investigated the irradiation of codfish, rice, and a macerated meat product with x rays produced by an electron linear accelerator that generated electrons at energies up to 12 MeV and predominately at 8 MeV (Ref. 4). These foods received radiation doses ranging from 8.8 to 14 kGy. Induced activities in the foods were reported to be approximately the same as natural background levels, and dropped quickly. The report also summarized the results from another study in which induced activities in fresh meat and in meat ash were measured after being irradiated with x rays generated at 7.3 MeV and 8.1 MeV at doses of 15 kGy and 8.6 kGy, respectively. Based on the measured activity from the two experiments and assuming a consumption of 40 kg/y of irradiated meat and a 24-hour delay time between irradiation and consumption, the total annual dose from meat due to treatment with higher energy x rays was determined to be 0.24 to 0.29×10^{-3} mSv/yr, a dose about 1,500 times lower than the 0.39 mSv received per year from consumption of food due to naturally occurring radionuclides (Ref. 3). Because most meat would be consumed more than 24 hours after treatment, the annual dose from the irradiated meat would be far less than the dose indicated from these experiments.

ORNL evaluated the information in the IAEA report. ORNL estimated induced activities in beef irradiated to 15 kGy with 7.5 MeV x rays and the resultant dose from consumption of the treated food (Ref. 3). ORNL used the elemental composition of beef for their analysis because its composition is similar both to that of the reference food used in the IAEA report and to food in general. From this information, ORNL determined induced radioactivity in beef and used this to estimate a potential radiation dose to humans from consumption of the food. The annual effective dose based on consumption of 40 kg/yr of beef was calculated to be 0.4×10^{-3} mSv, which is approximately 1,000 times less than the annual effective dose from consumption of foods due to naturally occurring radioactivity, and is consistent with the results from both the IAEA report and the Gregoire et al. report. In addition to beef, ORNL also calculated the effective annual dose from consumption of pork, poultry, and eggs treated with 7.5 MeV x rays and an absorbed dose of 15 kGy, ORNL determined that based on the average quantity of beef, pork, poultry, and eggs consumed in a year, the total effective annual human exposure from consumption of these irradiated foods would be 1.0×10^{-3} mSv/yr, which is about 400 times less than the 0.39 mSv/yr that people receive due to natural radioactivity in food. It is also important to note that this estimated exposure is highly conservative because it assumes the following: (1) That all of the beef, pork, poultry, and eggs that a person consumes in a year has been irradiated, (2) that these foods are consumed within 24 hours after irradiation, and, (3) that such foods would be treated with an average dose of 15 kGy, which is significantly higher than both the currently maximum permitted dose for these foods as well as doses that would be practical to apply to foods in commerce.

The results discussed previously considered potential radiation exposure for humans from consumption of various foods irradiated with high energy x rays. Although foods other than those that were studied may be irradiated with 7.5 MeV x rays, the

[1] Thirty kGy is close to a sterilizing dose. Foods, generally, would not be irradiated at such a high dose.

[2] The concentrations of elements in the reference food were chosen to be reasonably close to those of meat because, compared to other foods, meat is likely to be the food that receives the highest doses and that is consumed in the largest quantities. Although the concentrations of trace elements in foods can vary significantly, the difference in the radiation exposure to humans from consumption of one irradiated food and another food due to these variances would be insignificant.

compositions of the foods that were considered are representative of foods in general. Even at absorbed doses that are higher than those normally used in practice, the results clearly show that any radioactivity that may be induced in any food treated with 7.5 MeV x rays will be trivially low and that any potential human exposure due to consumption of irradiated food will be inconsequential compared to that from radionuclides that are present naturally in food.

C. The Need to Limit the X-Ray Target Material

Neutrons emitted from the x-ray target in the x-ray generator can also enter food and induce radioactivity. Therefore, FDA considered whether there is a need to specify or limit the x-ray target material to minimize neutron production from this source. Materials with photoneutron threshold energies below 7.5 MeV can produce photoneutrons, which could also be captured in the foods being irradiated. The petitioner has proposed the use of tantalum and gold as x-ray target materials. The x-ray energy levels needed to eject a neutron from the two common isotopes of tantalum (Ta-180 and Ta-181) are 6.6 and 7.6 MeV, respectively, but the neutron production from 7.5 MeV x rays is insignificant, and considerably less than from tungsten, a common x-ray target material (Refs. 1 and 3). Gold also does not produce significant numbers of neutrons when impinged with 7.5 MeV x rays (Ref. 1). Therefore, FDA concludes that tantalum and gold are acceptable x-ray target materials for the proposed use and is specifying these two x-ray target materials as a condition of safe use for machine sources of 7.5 MeV x rays.

IV. Conclusion of Safety

FDA has evaluated the data submitted in the petition and other relevant material and concludes that any added radioactivity in food from the use of 7.5 MeV x rays will be trivial compared to that from radionuclides that are present naturally in food. Therefore, the agency concludes that the proposed use of 7.5 MeV x rays for treating food is safe and that the conditions listed in § 179.26 should be amended as set forth in this document.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching the agency's decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

V. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the notice of filing for FAP 3M4745 (68 FR 12087). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

VI. Paperwork Reduction Act of 1995

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

VII. Objections

Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (see **ADDRESSES**) written or electronic objections by (see **DATES**). Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents are to be submitted and are to be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VIII. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. International Atomic Energy Agency, ''Natural and Induced Radioactivity in Food,'' IAEA–TECDOC–1287, Food and Environmental Protection Section, IAEA, Vienna, 2002.

2. Gregoire, O., Cleland, M. L., Wakeford, Mittendorfer, et al., ''Radiological Safety of Food Irradiation With High Energy X-Rays: Theoretical Expectations and Experimental Evidence,'' 2002.

3. Easterly, C. E., Eckerman, K. F., Ross, R. H., et al., ''Assessment of Petition to Increase the Maximum X-Ray Energy to 7.5 MeV from the Value of 5.0 MeV for the Treatment of Food by Ionizing Radiation,'' ORNL–2003–1, Oak Ridge National Laboratory, Life Sciences Division, 2003.

4. Wakeford, C. A., Blackburn R., and Swallow, A. J., ''Induction and Detection of Radioactivity in Foodstuffs Irradiated With 10 MeV Electrons and X-Rays,'' Radiation Physics and Chemistry, vol. 38, No. 1, pp. 29–38, 1991.

List of Subjects in 21 CFR Part 179

Food additives, Food labeling, Food packaging, Radiation protection, Reporting and recordkeeping requirements, Signs and symbols.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 179 is amended as follows:

PART 179—IRRADIATION IN THE PRODUCTION, PROCESSING AND HANDLING OF FOOD

■ 1. The authority citation for 21 CFR part 179 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 348, 373, 374.

■ 2. Section 179.26 is amended by revising paragraph (a)(3) and by adding paragraph (a)(4) to read as follows:

§ 179.26 Ionizing radiation for the treatment of food.

* * * * *

(a) * * *

(3) X rays generated from machine sources at energies not to exceed 5 million electron volts (MeV), except as permitted by paragraph (a)(4) of this section.

(4) X rays generated from machine sources using tantalum or gold as the target material and using energies not to exceed 7.5 (MeV).

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Dated: December 14, 2004.

Leslye M. Fraser,

Director, Office of Regulations and Policy, Center for Food Safety and Applied Nutrition.

[FR Doc. 04–28043 Filed 12–22–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Financial Crimes Enforcement Network

31 CFR Part 103

Interpretive Release No. 2004–02—Unitary Filing of Suspicious Activity and Blocking Reports

AGENCY: Financial Crimes Enforcement Network (''FinCEN''), Department of the Treasury.

ACTION: Final rule; interpretive release.

SUMMARY: This FinCEN interpretive guidance clarifies that reports filed with the Department of the Treasury's Office of Foreign Assets Control (''OFAC'') of blocked transactions with Specially Designated Global Terrorists, Specially Designated Terrorists, Foreign Terrorist Organizations, Specially Designated Narcotics Trafficker Kingpins, and Specially Designated Narcotics Traffickers will be deemed by FinCEN to fulfill the requirement to file suspicious activity reports on such transactions for purposes of FinCEN's suspicious activity reporting rules. However, the filing of a blocking report with OFAC will not be deemed to satisfy a financial institution's obligation to file a suspicious activity report if the transactions would be reportable under FinCEN's suspicious activity reporting rules even if there were no OFAC match. Moreover, to the extent that the financial institution is in possession of information not included on the blocking report filed with OFAC, a separate suspicious activity report should be filed with FinCEN including that information.

DATES: This final rule is effective December 23, 2004. The **DATES** section of the rule published on December 14, 2004, at 69 FR 74439 is corrected to read as follows:

DATES: Appendix C is added to part 103 effective December 14, 2004; however, Release 2004–01 is not effective until June 13, 2005.

FOR FURTHER INFORMATION CONTACT: Regulatory Policy and Programs Division, 1–800–949–2732, Financial Crimes Enforcement Network.

SUPPLEMENTARY INFORMATION: FinCEN is publishing this interpretation to clarify that the filing of required blocking reports with OFAC on transactions involving an individual or entity designated as a Specially Designated Global Terrorist, Specially Designated Terrorist, Foreign Terrorist Organization, Specially Designated Narcotics Trafficker Kingpin, or Specially Designated Narcotics Trafficker shall be deemed to satisfy the requirement, under existing and any forthcoming suspicious activity reporting regulations, that financial institutions file suspicious activity reports based on the fact of such a match.

List of Subjects in 31 CFR Part 103

Authority delegations (government agencies), Banks, Banking, Currency, Investigations, Reporting and recordkeeping requirements.

Department of the Treasury

1 CFR Chapter I

Authority and Issuance

■ For the reasons set forth in the preamble, part 103 of title 31 of the Code of Federal Regulations is amended as follows:

PART 103—FINANCIAL RECORDKEEPING AND REPORTING OF CURRENCY AND FOREIGN TRANSACTIONS

■ 1. The authority citation for part 103 continues to read as follows:

Authority: 12 U.S.C. 1829b and 1951–1959; 31 U.S.C. 5311–5314 and 5316–5332; title III, sec. 312, 313, 314, 319, 326, 352. Pub. L. 107–56, 115 Stat. 307, 21 U.S.C. 1786(q).

■ 2. Part 103 is amended by adding a new Intrepretive Release at the end of Appendix C to read as follows:

APPENDIX C TO PART 103—INTERPRETIVE RULES

* * * * *

Release No. 2004–02

This FinCEN interpretive guidance clarifies that reports filed with the Department of the Treasury's Office of Foreign Assets Control (''OFAC'') of blocked transactions with Specially Designated Global Terrorists, Specially Designated Terrorists, Foreign Terrorist Organizations, Specially Designated Narcotics Trafficker Kingpins, and Specially Designated Narcotics Traffickers will be deemed by FinCEN to fulfill the requirement to file suspicious activity reports on such transactions for purposes of FinCEN's suspicious activity reporting rules. However, the filing of a blocking report with OFAC will not be deemed to satisfy a financial institution's obligation to file a suspicious activity report if the transactions would be reportable under FinCEN's suspicious activity reporting rules even if there were no OFAC match. Moreover, to the extent that the financial institution is in possession of information not included on the blocking report filed with OFAC, a separate suspicious activity report should be filed with FinCEN including that information.

Background

The Bank Secrecy Act authorizes the Secretary of the Treasury to require financial institutions to report ''any suspicious transaction relevant to a possible violation of law or regulation.'' [1] Under this authority, FinCEN has issued regulations requiring banks, securities broker-dealers, introducing brokers, casinos, futures commission merchants, and money services businesses, to report suspicious activity that meets a particular dollar threshold.[2] Each rule includes filing procedures requiring that a suspicious transaction shall be reported by completing a suspicious activity report and filing it with FinCEN in a central location to be determined by FinCEN. Generally, the rules provide a financial institution with thirty days from the date of the initial detection of suspicious activity to file a report, with an additional thirty days if the financial institution is unable to identify a suspect. Reports are filed on forms developed for each industry subject to the reporting requirement.[3]

OFAC administers and enforces economic and trade sanctions based on U.S. foreign policy and national security goals against targeted foreign countries, terrorists, international narcotics traffickers, and those engaged in activities related to the proliferation of weapons of mass destruction. OFAC's Reporting, Procedures and Penalties Regulations at 31 CFR part 501 require U.S. financial institutions to block and file reports on accounts, payments, or transfers in which an OFAC-designated country, entity, or individual has any interest.[4] These reports must be filed with OFAC within ten business days of the blocking of the property.[5]

Prior Guidance

Transactions involving an individual or entity designated on OFAC's list of Specially Designated Nationals and Blocked Persons as a global terrorist, terrorist, terrorist organization, narcotics trafficker, or narcotics kingpin [6] may be in furtherance of a criminal act, and therefore relevant to a possible violation of law. Thus, blocking reports related to such persons also describe

[1] *See* 31 U.S.C. 5318(g)(1).

[2] See 31 CFR 103.17–21. The threshold for most financial institutions is $5,000; transactions conducted at points of sale for money services businesses have a reporting threshold of $2,000. See 31 CFR 103.20.

[3] See TD F 90–22.47 (depository institutions); TD F 22.56 (money services businesses); FinCEN Form 101 (securities and futures industries); FinCEN Form 102 (casinos and card clubs).

[4] 31 CFR 501.603.

[5] 31 CFR 501.603(b)(1)(i).

[6] The specific designations are as follows: Specially designated terrorist; foreign terrorist organization; specially designated global terrorist; specially designated narcotics trafficker; specially designated narcotics trafficker kingpin. *See* 31 CFR parts 595, 597, 598 and the Foreign Narcotics Kingpin Act, 21 U.S.C. 1901–08, 8 U.S.C. 1182. These categories of designations are subject solely to blocking requirements.