Authority: 5 U.S.C. 551–558, 701–706; 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–397, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

§ 10.20 [Amended]

2. Section 10.20 *Submission of documents to Dockets Management Branch; computation of time; availability for public disclosure* is amended by adding in paragraph (c)(1)(iii) the word ''or'' after the word ''available;'', by removing in paragraph (c)(1)(iv) the words ''agency; or'' and adding in its place the word ''agency.'', and by removing paragraph (c)(1)(v).

PART 12—FORMAL EVIDENTIARY PUBLIC HEARING

3. The authority citation for 21 CFR part 12 continues to read as follows:

Authority: 21 U.S.C. 141–149, 321–393, 467f, 679, 821, 1034; 42 U.S.C. 201, 262, 263b–263n, 264; 15 U.S.C. 1451–1461; 5 U.S.C. 551–558. 701–721; 28 U.S.C. 2112.

§ 12.22 [Amended]

4. Section 12.22 *Filing objections and requests for a hearing on a regulation or order* is amended by adding in paragraph (a)(5)(i)(*a*) the word ''or'' after the word ''available;'', by removing in paragraph (a)(5)(i)(*b*) the words ''agency; or'' and adding in its place the word ''agency.'', and by removing paragraph (a)(5)(i)(*c*).

PART 510—NEW ANIMAL DRUGS

5. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.3 [Amended]

6. Section 510.3 *Definitions and interpretations* is amended by removing paragraph (l).

§ 510.95 [Removed and Reserved]

7. Section 510.95 *Designated journals* is removed and reserved.

Dated: November 30, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–31907 Filed 12–9–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 179

[Docket No. 94F–0455]

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 to provide for the safe use of X-radiation, produced by operation of X-ray tubes at energy levels of 500 kilovolt peak or lower, to inspect food. This action is in response to a petition filed by American Science and Engineering, Inc.

DATES: This regulation is effective December 10, 1999; written objections and request for a hearing by January 10, 2000.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Felicia Binion Williams, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3122.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of January 13, 1995 (60 FR 3249), FDA announced that a food additive petition (FAP 5M4438) had been filed by American Science and Engineering, Inc., 829 Middlesex Turnpike, Billerica, MA 01821, formerly 40 Erie St., Cambridge, MA 02139–4286. The petitioner proposed that the food additive regulations in § 179.21 *Sources of radiation used for inspection of food, for inspection of packaged food, and for controlling food processing* (21 CFR 179.21), be amended to provide for the safe use of X-radiation, produced by operation of X-ray tubes at energy levels of 500,000 electron volts (500 keV) or lower, to inspect cargo containers that may contain food. The current regulation limits the operation of X-ray tubes to energy levels of 300,000 electron volts (300 keV) peak or lower.

FDA has evaluated the data and information in the petition and other relevant material, and notes that information in the petition establishes that an extension of the upper limit on the energy level is necessary in order to be able to inspect large cargo containers using X-ray tubes. The data and information available to the agency establish that the maximum absorbed dose expected as a result of the petitioned use of X-radiation is 50 micrograys. This level of absorption is well below 10 grays, a level established as safe, by prior agency reviews.

The agency concludes that the proposed use of X-radiation, produced by operation of X-ray tubes at energy levels of 500 keV or lower, to inspect food, is safe and that the conditions listed in § 179.21 should be amended as set forth below. In addition, FDA is making a minor editorial change in the wording of the regulation to reflect the fact that operating voltage of the X-ray source should be described as a voltage, rather than an energy level. This change is more technically accurate and does not change the requirements of the current regulation.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its 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 listed above. 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.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

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.

Any person who will be adversely affected by this regulation may at any time on or before January 10, 2000, file with the Dockets Management Branch (address above) written objections thereto. 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 shall be submitted and shall 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

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 179.21(a)(1) is revised to read as follows:

§ 179.21 Sources of radiation used for inspection of food, for inspection of packaged food, and for controlling food processing.

* * * * *

(a) * * *

(1) X-ray tubes producing X-radiation from operation of the tube source at a voltage of 500 kilovolt peak or lower.

* * * * *

Dated: November 26, 1999.

L. Robert Lake,

Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.

[FR Doc. 99–32001 Filed 12–9–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

New Animal Drugs; Change of Sponsor Address

AGENCY: Food and Drug Administration

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor address for Hoechst Roussel Vet.

DATES: This regulation is effective December 10, 1999.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0213.

SUPPLEMENTARY INFORMATION: Hoechst Roussel Vet, 30 Independence Blvd., P.O. Box 4915, Warren, NJ 07059, has informed FDA of a change of sponsor address to Perryville Corporate Park III, P.O. Box 4010, Clinton, NJ 08809–4010. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) to reflect the change of sponsor address.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A), because it is a rule of ''particular applicability.'' Therefore, it is not subject to congressional review requirements in 5 U.S.C 801–808.

List of Subjects in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. Section 510.600 is amended in the table in paragraph (c)(1) by revising the entry for ''Hoechst Roussel Vet'' and in the table in paragraph (c)(2) by revising the entry for ''012799'' to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * *	* * * *
Hoechst Roussel Vet, Perryville Corporate Park III, P.O. Box 4010, Clinton, NJ 08809–4010.	012799
* * *	* * * *

(2) * * *

Drug labeler code	Firm name and address
* * *	* * * *
012799	Hoechst Roussel Vet, Perryville Corporate Park III, P.O. Box 4010, Clinton, NJ 08809–4010.
* * *	* * * *