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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 556 and 558

Animal Drugs, Feeds, and Related Products; Diclazuril

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Schering-Plough Animal Health Corp. The NADA provides for the use of a Type A medicated article containing diclazuril for use in manufacturing a Type C medicated feed indicated for the prevention of coccidiosis in broiler chickens.

EFFECTIVE DATE: July 2, 1999.

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 1095 Morris Ave., Union, NJ 07083, filed NADA 140–951, which provides for the use of a Type A medicated article containing 0.2 percent of diclazuril (Clinacox™) for use in manufacturing a Type C medicated feed indicated for the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mitis* (*mivati*), and *E. maxima*. Because diclazuril is effective against *E. maxima* later in its life cycle, subclinical intestinal lesions may be present for a short time after infection. Diclazuril was shown in studies to reduce lesion scores and improve performance and health of birds challenged with *E. maxima*. The NADA is approved as of April 21, 1999, and the regulations are amended in 21 CFR part 558 by adding § 558.198 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

Also, the regulations are amended in 21 CFR part 556 by adding § 556.175 to establish tolerances for diclazuril residues in the edible tissues of chickens and to establish an acceptable daily intake (ADI) for total diclazuril residues. The ADI represents the total amount of drug residue that can safely be consumed by humans every day.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity for the use of diclazuril in chicken feed beginning April 21, 1999, because no active ingredient (including any ester or salt of the active ingredient) has been approved in any other application.

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 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 the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects

21 CFR Part 556

Animal drugs, Foods.

21 CFR Part 558

Animal drugs, Animal feeds.

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 parts 556 and 558 are amended as follows:

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

1. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

2. Section 556.175 is added to subpart B to read as follows:

§ 556.175 Diclazuril.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of diclazuril is 25 micrograms per kilogram of body weight per day.

(b) *Tolerances.* (1) Chickens: Tolerances are established for residues of parent diclazuril at 0.5 part per million (ppm) in muscle, 3 ppm in liver, and 1 ppm in skin/fat.

(2) [Reserved]

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

3. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

4. Section 558.198 is added to subpart B to read as follows:

§ 558.198 Diclazuril.

(a) *Approvals.* Type A medicated article: 0.2 percent of diclazuril to 000061 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See § 556.175 of this chapter.

(c) [Reserved]

(d) *Conditions of use.* It is used in broiler chickens as follows:

(1) *Amount.* 1 part per million (ppm).

(2) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mitis* (*mivati*), and *E. maxima*. Because diclazuril is effective against *E. maxima* later in its life cycle, subclinical intestinal lesions may be present for a short time after infection. Diclazuril was shown in studies to reduce lesion scores and

improve performance and health of birds challenged with *E. maxima*.

(3) *Limitations.* Feed continuously. Not for use in hens producing eggs for human food.

Dated: June 4, 1999.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 99–16836 Filed 7–1–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1020

[Docket No. 98N–0877]

Medical Devices; Performance Standard for Diagnostic X–Ray Systems; Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule that amends the diagnostic x-ray systems performance standard for dental panoramic systems and mammography systems. This rule exempts panoramic dental x-ray units from the requirement that they be manufactured with exposure timers that automatically reset to zero upon premature termination of an exposure. Removing the automatic timer reset requirement will not compromise the quality of the radiographic image and will protect patients from being subject to unnecessary radiation due to repeat radiographs. This action also is intended to align the performance standard for mammography systems with the equipment requirements issued under the Mammography Quality Standards Act of 1992 (the MQSA).

EFFECTIVE DATE: September 30, 1999.

FOR FURTHER INFORMATION CONTACT: Richard V. Kaczmarek, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–0865.

SUPPLEMENTARY INFORMATION:

I. Background

A. Panoramic Dental Radiograph

The requirements in § 1020.31 (21 CFR 1020.31) apply to diagnostic x-ray systems, including those used for dental radiography and mammography. Based on information from manufacturers, FDA had determined that the timer requirement in § 1020.31(a)(2)(i) should not apply to panoramic dental units. As a result of that determination, FDA exercised its enforcement discretion and did not apply the timer requirement to panoramic dental units. Some States had adopted local standards that were identical in language to FDA's regulation, but did not exempt panoramic dental units from the timer requirement because those units were not expressly exempted in the Federal regulation. Those States were applying the timer requirement to dental panoramic units. To correct this inconsistency, FDA has amended the regulations to expressly exempt panoramic dental units from the timer requirement in § 1020.31(a)(2)(i). This change should lead to consistency among government requirements.

B. Mammography X–Ray Devices

The recent passage of the MQSA (Pub. L. 102–539) and issuance of the interim and final MQSA regulations have focussed attention on the mammography equipment requirements contained in 21 CFR part 1020. Although the MQSA is directed to facility requirements for maintaining mammography quality, both the interim and the final MQSA regulations address x-ray equipment that is also subject to the performance standard for diagnostic x-ray systems (58 FR 67558 and 58 FR 67565, December 21, 1993; and 62 FR 55976, October 28, 1997). The MQSA and FDA's regulations governing mammography establish quality standards for facilities performing mammography to ensure safe, reliable, and accurate mammography nationwide. FDA wanted to ensure that the standards applying to radiation emitting electronic products, including mammography equipment, and those applying to the facilities that use such equipment were in accord. To bring the standards into harmony, FDA has amended its performance standard for diagnostic x-ray systems.

The MQSA standards also address the proper viewing of mammography films. The standard practice is that these films be read on view boxes (light boxes) with the ambient room light levels reduced. Unexposed film areas and parts of the light box not covered by exposed film should be masked to prevent the bright light surrounding the radiograph from interfering with reading the film.

Extending the x-ray field to expose the borders of the film simplifies the work of the radiologist and accreditation bodies because they have to create only one mask size, rather than having to create individualized masks for each facility. With the current practice being to irradiate the same area of the same sized film for all patients, there is little evidence that allowing the x-ray field to completely darken the film will significantly raise the radiation safety risk to the patient. FDA has amended the diagnostic x-ray systems standard to allow fixed aperture and variable aperture beam-limiting device (BLD) systems, to open up or adjust the field size to cover the entire film and thus reduce the need to provide a different mask for each film. In certain instances, limiting the x-ray field to the size of the breast may be considered to be advantageous. Practitioners still retain this option, which may result in improved imaging quality due to the reduction of scattered radiation.

To reduce unnecessary radiation exposure to the patient beyond the plane of the image receptor, FDA has requirements for x-ray field limitation and alignment. In the past, all systems in use for mammography had fixed aperture plates for x-ray field limitation. The advent of the variable aperture BLD for mammography is potentially a problem with respect to the primary barrier requirement if a BLD is opened so that the useful beam extends beyond the primary barrier provided by the image receptor support device. To prevent this problem, a variable aperture BLD must provide some restriction on the maximum field size to ensure that the entire useful beam at the plane of the image receptor is contained within the image receptor support device, which is also a primary barrier. In other words, for a fixed aperture or a variable aperture BLD with the collimator opened as wide as possible, the entire useful beam should not extend beyond the barrier, at any available source-image receptor distance (SID), except at the chest wall side, and the exposure level 5 centimeters beyond this barrier should not exceed 2.58×10^{-8} coulombs per kilogram (C/k) (0.1 milliroentgen (mR)) per exposure. This requirement is in agreement with the International Electrotechnical Commission (IEC) draft standard for mammography systems (IEC 62B/60601–2–45).

II. The Final Rule

FDA believes that the final rule establishes reasonable requirements that can be implemented by the regulated industry without unnecessary burden. None of the comments on the proposed rule requested that FDA revise any of the changes proposed.

A. Panoramic Dental Radiograph

The final rule exempts panoramic dental x-ray units from the requirement in § 1020.31(a)(2)(i) that they be