We find that, during Phase 1, a request for transmission service made after 2:00 p.m. of the day preceding the commencement of such service, will be ''made on the OASIS'' if it is made directly on the OASIS, or, if it is made by facsimile or telephone *and* promptly (within one hour) posted on the OASIS by the Transmission Provider. In all other circumstances, requests for transmission service must be made exclusively on the OASIS.

The Commission orders: The request of the How Working Group for a clarification of the OASIS Final Rule is hereby granted, as discussed in the body of this order.

By the Commission.

Lois D. Cashell,

Secretary.

[FR Doc. 97–140 Filed 1–3–97; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 529

Certain Other Dosage Form New Animal Drugs; Gentamicin Sulfate Intrauterine Solution

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 an abbreviated new animal drug application (ANADA) filed by Phoenix Pharmaceutical, Inc. The ANADA provides for the use of a generic gentamicin sulfate intrauterine solution for control of bacterial infections of the uterus in horses (metritis) and as an aid in improving conception in mares with uterine infections caused by bacteria sensitive to gentamicin.

EFFECTIVE DATE: January 6, 1997.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1617.

SUPPLEMENTARY INFORMATION: Phoenix Pharmaceutical, Inc., 4621 Easton Rd., P.O. Box 6457, Fairleigh Station, St. Joseph, MO 64506–0457, is the sponsor of ANADA 200–137, which provides for the use of a generic gentamicin sulfate intrauterine solution (100 milligrams/milliliter (mg/mL)) for control of bacterial infections of the uterus in horses (metritis) and as an aid in improving conception in mares with uterine infections caused by bacteria sensitive to gentamicin.

Approval of ANADA 200–137 for Phoenix Pharmaceutical's gentamicin sulfate intrauterine solution (100 mg/mL gentamicin) is as a generic copy of Schering's Gentocin® Solution (100 mg/mL gentamicin) in NADA 046–724. The ANADA is approved as of November 13, 1996, and the regulations are amended in 21 CFR 529.1044a to reflect the approval. The basis for approval is discussed in the freedom of information summary.

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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(i) 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.

List of Subjects in 21 CFR Part 529

Animal drugs.

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 529 is amended to read as follows:

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 529 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 529.1044a [Amended]

2. Section 529.1044a *Gentamicin sulfate intrauterine solution* is amended in paragraph (b) by removing ''000061, 000856, 000864, 054273, and 057561'' and adding in its place ''000061, 000856, 000864, 054273, 057319, and 057561''.

Dated: December 23, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–185 Filed 1–3–97; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 579

[Docket No. 92F–0317]

Food Additives; Irradiation in the Production, Processing, and Handling of Animal Feed and Pet Food; Ionizing Radiation for Treatment of Poultry Feed or Poultry Feed Ingredients

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; response to objections and denial of requests for a hearing.

SUMMARY: The Food and Drug Administration (FDA) is responding to objections and is denying the requests for a hearing on the final rule that amended the food additive regulations (animal use) to provide for the safe use of gamma radiation from cobalt-60 for rendering complete poultry feeds or poultry feed ingredients salmonella negative. Four parties filed objections to the final rule and submitted requests for a hearing requesting approval of additional energy sources for this use. After reviewing their submissions, FDA has concluded that the objections do not raise issues of material fact concerning the approval that justify granting a hearing. Therefore, FDA is denying the requests for a hearing.

DATES: The final rule published in the Federal Register of September 28, 1995, at 60 FR 50098 is effective.

FOR FURTHER INFORMATION CONTACT: George Graber, Center for Veterinary Medicine (HFV–220), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1724.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the Federal Register of August 20, 1992 (57 FR 37825), FDA announced that a food additive petition (animal use) (FAP 2216) had been filed by Nordion International, Inc., 447 March Rd., P.O. Box 13500, Kanata, ON, Canada K2K lX8. The petition proposed that the feed irradiation regulations be amended to provide for the safe use of gamma radiation from cobalt-60, not to exceed 25 kiloGrays (kGy) (2.5 Mrad), to control salmonella in complete poultry (chickens, turkeys, ducks, geese, cornish hens, pheasant, quail, and fowl) feeds or feed ingredients. The notice of filing of FAP 2216 provided for a 60-day comment period. No comments were received.

In a final rule published in the Federal Register of September 28, 1995 (60 FR 50098), FDA amended the animal feed and pet food irradiation

regulations to provide for the use of 2 to 25 kGy of gamma radiation from sealed units of cobalt-60 to render complete poultry feeds or poultry feed ingredients salmonella negative. The rule added new § 579.40 (21 CFR 579.40) to reflect the new feed additive use.

II. Objections and Requests for a Hearing

AECL Technologies, Inc., AECL Accelerators, 20 Little Lane, Hauppage, NY 11788; E–BEAM Services, Inc., 32 Melrich Rd., Cranbury, NJ 08512; Department of Animal Sciences, Texas A&M University, College Station, TX 77843–2471; and Secretariat of the International Consultative Group on Food Irradiation; each filed objections to the final rule citing failure of that rule to provide for additional energy sources including gamma rays from cesium-137, machine generated electrons not to exceed 10 million electron volts, and machine generated x-rays not to exceed 5 million electron volts, in addition to the use of gamma radiation from cobalt-60. The petition supported use of cobalt-60 energy sources. Information filed in the objections did not object to the conditions of approval of the petition, but the information filed in the objections supported additional energy sources not previously considered. Such information should be the subject of a separate food additive petition filed in accordance with 21 CFR 571.1 to support amending the regulations to provide for the use of these additional energy sources.

III. Standards for Granting a Hearing

Section 409(b)(5) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(b)(5)) provides for publication of a notice, in general terms, of filing of a food additive petition. That notice contains provisions for a 60-day comment period. Section 409(f)(1) of the act provides for a 30-day comment period after publication of an order (final rule) relating to approval of a food additive petition to permit any person adversely affected by such an order to file objections, specifying with particularity the provisions of the order ''deemed objectionable, stating reasonable grounds therefor,'' and requesting a public a hearing upon such objections.

Specific criteria for determining whether a request for a hearing is justified are set forth in § 12.24(b) (21 CFR 12.24(b)). A hearing will be granted if the material submitted shows that:

(1) There is a genuine and substantial issue of fact for resolution at a hearing. A hearing will not be granted on issues of policy or law.

(2) The factual issue can be resolved by available and specifically identified reliable evidence. A hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions.

(3) The data and information submitted, if established at a hearing, would be adequate to justify resolution of the factual issue in the way sought by the person. A hearing will be denied if the Commissioner concludes that the data and information submitted are insufficient to justify the factual determination urged, even if accurate.

(4) Resolution of the factual issue in the way sought by the person is adequate to justify the action requested. A hearing will not be granted on factual issues that are not determinative with respect to the action requested, e.g., if the Commissioner concludes that the action would be the same even if the factual issue were resolved in the way sought * * *.

(5) The action requested is not inconsistent with any provision in the act or any regulation in this chapter particularizing statutory standards. The proper procedure in those circumstances is for the person requesting the hearing to petition for an amendment or waiver of the regulation involved.

(6) The requirements in other applicable regulations, e.g., §§ 10.20, 12.21, 12.22, 314.200, 314.300, 514.200, and 601.7(a), and in the notice promulgating the final regulation or the notice of opportunity for hearing are met.

FDA may deny a request for a hearing if the objections to the regulation do not raise genuine and substantial issues of fact that can be resolved at a hearing (*Community Nutrition Institute* v. *Young*, 773 F.2d 1356, 1364 (D.C. Cir. 1985), *cert. denied*, 475 U.S. 1123 (1986)).

A party seeking a hearing is required to meet a ''threshold burden of tendering evidence suggesting the need for a hearing'' (*Costle* v. *Pacific Legal Foundation*, 445 U.S. 198, 214–215 (1980) reh. den., 445 U.S. 947 (1980), citing *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 620–621 (1973)). An allegation that a hearing is necessary to ''sharpen the issues'' or to ''fully develop the facts'' does not meet this test (*Georgia Pacific Corp.* v. *U.S. E.P.A.*, 671 F.2d 1235, 1241 (9th Cir. 1982)). If a request for a hearing fails to identify any factual evidence that would be the subject of a hearing, then there is no basis for holding a hearing. In judicial proceedings, a court is authorized to issue summary judgment without an evidentiary hearing whenever it finds that there are no genuine issues of material fact in dispute, and a party is entitled to judgment as a matter of law. (See Rule 56, Federal Rules of Civil Procedure.) The same principle applies in administrative proceedings.

A hearing request must not only contain evidence, but that evidence should raise a material issue of fact upon which a meaningful hearing might be held (*Pineapple Growers Association* v. *FDA*, 673 F.2d 1083, 1085 (9th Cir. 1982)). Where the issues raised in the objection are, even if true, legally insufficient to alter the decision, the agency need not grant a hearing (*Dyestuffs and Chemicals, Inc.* v. *Flemming*, 271 F.2d 281 (8th Cir. 1959) *cert. denied*, 362 U.S. 911 (1960)). FDA need not grant a hearing in each case where an objector submits additional information or posits a novel interpretation of existing information. (See *United States* v. *Consolidated Mines & Smelting Co.*, 455 F.2d 432 (9th Cir. 1971).) In other words, a hearing is justified only if the objections are made in good faith and if they ''draw in question in a material way the underpinnings of the regulation at issue'' (*Pactra Industries* v. *CPSC*, 555 F.2d 677 (9th Cir. 1977)). Finally, courts have uniformly recognized that a hearing need not be held to resolve questions of law or policy. (See *Citizens for Allegan County, Inc.* v. *FPC*, 414 F.2d 1125 (D.C. Cir. 1969); *Sun Oil Co.* v. *FPC*, 256 F.2d 233, 240 (5th Cir.), *cert. denied*, 358 U.S. 872 (1958).)

In sum, a hearing request should present sufficient credible evidence to raise a material issue of fact, and that evidence must be adequate to resolve the issue as requested and to justify the action requested.

IV. Analysis of Objections and Response to Requests for a Hearing

FDA is denying the parties' request for a hearing on their objections for two reasons. First, under § 12.24(b)(5), FDA will not grant a hearing if the action requested is inconsistent with any provision in the act or any FDA regulation. The parties' requested action is inconsistent with the act and FDA's regulations, because the parties have raised an issue regarding additional energy sources for this food additive use that was not previously presented in the petition and have requested a hearing on the issue. Under the act and FDA's regulations, the scope of a proceeding for approval of a food additive use is limited to the terms and conditions of use set forth in the petition.

Under section 409(c) of the act, an action on a petition to establish a food additive use is based on the petition and other available information. The petition that led to the issuance of § 579.40 provided for use of gamma radiation from a cobalt-60 energy source for rendering complete poultry feeds or poultry feed ingredients salmonella

negative. FDA granted this petition, and in the preamble of the final rule (60 FR 50098), the agency specifically addressed each of the issues raised in evaluating the petition. The parties, however, have objected to the failure of the final rule to provide for additional energy sources, including gamma rays from cesium-137, machine generated electrons not exceeding 10 million electron volts, and machine generated x-rays not exceeding 5 million electron volts.

Under section 409(f)(1) of the act, any person adversely affected by a final rule may file objections thereto, specifying with particularity the provisions of the final rule deemed objectionable, stating reasonable grounds therefor, and requesting a public hearing upon such objections. However, there is nothing in the act or in FDA's regulations that suggests or implies that, or that authorizes, interested persons to use the opportunity to object as an opportunity to expand the authorized use of a food additive beyond that use sought in the petition. On the contrary, 21 CFR 571.6 requires that if, after a petition has been filed, the petitioner submits added information which constitutes a substantive amendment, the petition will be given a new filing date; and the review process will begin anew.

Thus, under the act and FDA's regulations, the scope of a proceeding for approval of a food additive use is limited to the terms and conditions of use set out in the petition. To the extent that a person who is not the petitioner seeks to extend the petitioned-for terms and conditions of use, the person must do so by a separate petition, not by objection to the final rule. To attempt to do so by objection to the final rule, or by comment on the notice of filing, is to attempt to act in a manner that is inconsistent with the act and FDA's regulations. The proper procedure, as stated in § 12.24(b)(5), is for the objecting parties to petition for amendment of § 579.40. Thus, the objecting parties have failed to justify a hearing on the requested action.

Second, under its regulations, FDA will not grant a hearing on the basis of mere allegations (§ 12.24(b)(2)). Consistent with this regulation, the relevant case law provides that where a party requesting a hearing only offers allegations without an adequate proffer to support them, the agency may properly disregard those allegations (*General Motors Corp.* v. *FERC*, 656 F.2d 791, 798 n.20 (D.C. Cir. 1981)). The objecting parties have failed to submit any evidence showing that failure to approve the use of additional energy sources will compromise the approved use of radiation emitted from cobalt-60. Thus, because the parties have failed to offer any support for their allegation, FDA concludes that this objection does not justify a hearing.

V. Summary and Conclusion

The agency is denying the objections and the requests for a hearing on the basis that the request is beyond the scope of the petitioned action and is appropriately resolved through the submission of a separate petition (§ 12.24(b)(5)) and the requested action could not be approved on the basis of a hearing, i.e., not to be granted based on allegations or general descriptions of positions and contentions (§ 12.24(b)(2)).

The filing of the objections and requests for a hearing does not affect the provisions of § 579.40 to which the objections were made.

In the absence of any other objections and requests for a hearing, the agency further concludes that this document constitutes final action on the objections and requests for a hearing received in response to the regulation as prescribed in section 409(f)(1) of the act (21 U.S.C. 348).

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 409 (21 U.S.C. 348)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.61), notice is given that the objections and the requests for a hearing filed in response to the final rule § 579.40 that was published in the Federal Register on September 28, 1995 (60 FR 50098), do not form a basis for further amendment of this final rule.

Dated: December 30, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–137 Filed 1–3–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF STATE

[Public Notice 2478]

22 CFR Part 42

Bureau of Consular Affairs; Visas: Documentation of Immigrants under the Immigration and Nationality Act, as Amended

AGENCY: Bureau of Consular Affairs, DOS.

ACTION: Final rule.

SUMMARY: The Violence Against Women Act of 1994 (Title IV of the Violent Crime Control and Law Enforcement Act of 1994, Pub. L. 103–322, 108 Stat. 1902, 1953–1955), amended section 204 of the Immigration and Nationality Act (INA) to allow certain spouses and children of citizens or lawful permanent resident aliens to self-petition for immediate relative and preference classifications. This rule adds classification symbols for this category of immigrants.

EFFECTIVE DATE: This rule takes effect on January 6, 1997.

ADDRESSES: Chief, Legislation and Regulation Division, Visa Office, Washington, D.C. 20522–1013.

FOR FURTHER INFORMATION CONTACT: Stephen K. Fischel, Chief, Legislation and Regulations Division, 202–663–1204.

SUPPLEMENTARY INFORMATION: Section 40701 of the Violence Against Women Act of 1994 accords aliens who have been battered and/or abused by a U.S. citizen or alien resident spouse or parent, and who have resided in the United States with that spouse or parent, the right to self-petition for immediate relative or family preference status. *Creation of new immigrant visa categories.*

This rule amends part 42, title 22 of the Code of Federal Regulations by adding the new visa symbols for these immigrant categories: IB1 through IB3, B11 and B12, B21 through B25, BX1 through BX3, and B31 through B33 to the list of immigrant visa symbols at § 42.11. Other minor editorial changes have been made throughout.

Final Rule

This rule will not have a significant impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act, 5 U.S.C. 605(b). This rule imposes no reporting or record-keeping action on the public subject to the Paperwork Reduction Act, 44 U.S.C. Chapter 35. No Federalism assessment is required under E.O. 12612. This rule has been reviewed as required by E.O. 12988. This rule is exempted from E.O. 12866 but has been reviewed to ensure consistency therewith. This rule is being promulgated as a final rule pursuant to the ''good cause'' provision of 5 U.S.C. sec. 553(b); notice and comment are not necessary in light of the fact that this rule merely establishes visa symbols and makes no substantive rule changes.

List of Subjects in 22 CFR Part 42

Classification of immigrants, Classification symbols, Visas.

Accordingly, part 42 to title 22 of the Code of Federal Regulations is amended to read as indicated below: