(d) *Transitional certification.* OTPs that before May 18, 2001 were the subject of a current, valid approval by FDA under 21 CFR, part 291 (contained in the 21 CFR parts 200 to 299 edition, revised as of July 1, 2000), are deemed to be the subject of a current valid certification for purposes of paragraph (a)(11) of this section. Such ''transitional certification'' will expire on August 17, 2001 unless the OTP submits the information required by paragraph (b) of this section to SAMHSA on or before August 17, 2001. In addition to this application, OTPs must certify with a written statement signed by the program sponsor, that they will apply for accreditation within 90 days of the date SAMHSA approves the second accreditation body. Transitional certification, in that case, will expire on May 19, 2003. SAMHSA may extend the transitional certification of an OTP for up to one additional year provided the OTP demonstrates that it has applied for accreditation, that an accreditation survey has taken place or is scheduled to take place, and that an accreditation decision is expected within a reasonable period of time (e.g., within 90 days from the date of survey). Transitional certification under this section may be suspended or revoked in accordance with § 8.14.

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[FR Doc. 01–6745 Filed 3–16–01; 8:45 am]

BILLING CODE 4160–20–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, and 522

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for two approved new animal drug applications (NADA's) from Wendt Laboratories, Inc., to First Priority, Inc.

DATES: This rule is effective March 19, 2001.

FOR FURTHER INFORMATION CONTACT: Norman J. Turner, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0214.

SUPPLEMENTARY INFORMATION: Wendt Laboratories, Inc., 100 Nancy Dr., Belle Plaine, MN 56011, has informed FDA that it has transferred to First Priority, Inc., 1585 Todd Farm Dr., Elgin, IL 60123, ownership of, and all rights and interests in NADA 48–646 for Therazone Injection and NADA 48–647 for Therazone Tablets. Accordingly, the agency is amending the regulations in 21 CFR 520.1720a and 522.1720 to reflect the transfer of ownership.

In addition, First Priority, Inc., has not been previously listed in the animal drug regulations as a sponsor of an approved application. At this time, 21 CFR 510.600(c) is being amended to add entries for the firm.

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 510

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

21 CFR Parts 520 and 522

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 parts 510, 520, and 522 are 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 alphabetically adding an entry for ''First Priority, Inc.'' and in the table in paragraph (c)(2) by numerically adding an entry for ''058829'' 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
* * * * * * *	
First Priority, Inc., 1585 Todd Farm Dr., Elgin, IL 60123	058829
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
058829	First Priority, Inc., 1585 Todd Farm Dr., Elgin, IL 60123.
* * * * * * *	

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 520 continues to read as follows:

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

§ 520.1720a [Amended]

4. Section 520.1720a *Phenylbutazone tablets and boluses* is amended in paragraph (b)(3) by removing ''015579'' and adding in its place ''058829''.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

5. The authority citation for 21 CFR part 522 continues to read as follows:

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

§ 522.1720 [Amended]

6. Section 522.1720 *Phenylbutazone injection* is amended in paragraph (b)(1) by removing ''015579'' and adding in its place ''058829''.

Dated: February 9, 2001.

Claire M. Lathers,

Director, Office of New Animal Drug Evaulation, Center for Veterinary Medicine.

[FR Doc. 01–6713 Filed 3–16–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF STATE

Bureau of Consular Affairs

22 CFR Part 42

[Public Notice 3555]

Visas: Documentation of Immigrants—International Broadcasters

AGENCY: Bureau of Consular Affairs, DOS.

ACTION: Interim rule with request for comments.

SUMMARY: This rule incorporates into existing regulation a new special immigrant visa classification for certain international broadcasting employees of the International Broadcasting Bureau of the Broadcasting Board of Governors or grantees of that Board. This addition to the regulation results from an amendment to the pertinent legislation. The change will permit certain broadcasting employees to receive immigrant visas and apply for entry into the United States as immigrants.

DATES: Effective date: This interim rule is effective on April 18, 2001.

Comment date: Written comments must be submitted on or before May 18, 2001.

ADDRESSES: Submit comments in duplicate to the Chief, Legislation and Regulations Division, Visa Services, Department of State, 20520–0106, (202) 663–1204, e-mail *odomhe@state.gov,* or fax at (202) 663–3898.

FOR FURTHER INFORMATION CONTACT: H. Edward Odom, Chief, Legislation and Regulations Division, Visa Services, Department of State, Washington, DC 20520–0106.

SUPPLEMENTARY INFORMATION:

What Is the Authority for This Rule?

Pub. L. 106–536 created a new class of special immigrants under INA 203(b)(4) for international broadcasting employees. Such aliens must be seeking to enter the United States to work as a broadcaster for the International Broadcasting Bureau of the Broadcasting Board of Governors, or for a grantee of the Broadcasting Board of Governors. The alien's accompanying spouse and child(ren) are entitled to derivative status. The law limits the number of immigrants in this category to 100 annually, excluding spouses and children for whom there is no numerical limitation.

Interim Rule

How Is the Department Amending its Regulation?

The Department is amending its regulation at 22 CFR 42.32 by adding a new paragraph (d)(8).

What Effect Will This Rule Have on Current Regulations?

This rule authorizes consular officers to accord fourth preference employment-based special immigrant classification to certain international broadcasters. As with other classes of fourth preference employment-based immigrants, the alien must be the beneficiary of an approved petition.

Administrative Procedure Act

The Department's implementation of this regulation as an interim rule is based upon the ''good cause'' exceptions found at 5 U.S.C. 553(b)(B) and (d)(3). As the amendment to the regulation simply implements without interpretation a legislative mandate that provides a benefit to aliens by extending special immigrant status to a specific class of aliens, the Department has determined that it is unnecessary to publish a proposed rule or to solicit comments from the public. In view of this benefit and since the amendment applies to visas made available in any fiscal year beginning on or after October 1, 2000, the rule will be made effective immediately upon publication in the **Federal Register**.

Regulatory Flexibility Act

The Department of State, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation and, by approving it, certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by state, local and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Act of 1996. This rule will not result in an annual effect on the economy of $100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Executive Order 12866

The Department of State does not consider this rule, to be a ''significant regulatory action'' under Executive Order 12866, section 3(f), Regulatory Planning and Review, and the Office of Management and Budget has waived its review process under section 6(a)(3)(A).

Executive Order 13132

This regulation will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with section 6 of Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.