TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Item	No. of Respondents	Annual Frequency per Response	Total Annual Records	Hours per Response	Total Hours
Request for Accreditation (First Year)	25	1	25	80	2,000
Request for Accreditation (Second Year)	10	1	10	15	150
Request for Accreditation (Third Year)	5	1	5	80	400
Total Hours					2,550

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA based these estimates on conversations with industry, trade association representatives, and internal FDA estimates. Our expectation is that 25 bodies will apply and meet the minimum standard for being accredited. Under MDUFMA, we can only accredit 15 persons during the first year. We expect that the lowest ranking 10 (the ones not accredited) will reapply the following year and will submit an updated application. Five new applicants may apply the third year. Once an organization is accredited, it will not be required to reapply.

Dated: July 2, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–17411 Filed 7–9–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Notice of Approval of New Animal Drug Applications; Chlortetracycline

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice that in 2001 it approved a supplemental new animal drug application (NADA) filed by Alpharma, Inc. The supplemental NADA provided for use of chlortetracycline Type A medicated articles to make Type B and Type C medicated swine feeds for the control of porcine proliferative enteropathies (ileitis). The applicable section of the regulation did not require amendment.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7571, e-mail: *jgotthar@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: In accordance with section 512(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(i)) and 21 CFR 514.105(a) and 514.106(a), FDA is providing notice that in 2001 it approved a supplemental NADA that was not the subject of a final rule. A final rule was not published because 21 CFR 558.128 did not require amendment.

On November 15, 2001, FDA approved a supplement filed by Alpharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024 to NADA 48–761 for AUREOMYCIN (chlortetracycline) Type A medicated articles. The supplemental NADA provided for use of AUREOMYCIN Type A medicated articles to make Type B and Type C medicated swine feeds for the control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline. No new data were submitted. The necessary amendment to 21 CFR 558.128 was made in a final rule (65 FR 45881, July 26, 2000) for the 2000 supplemental approval of the identical claim for Alpharma, Inc.'s CHLORMAX (chlortetracycline) Type A medicated articles, approved under NADA 046–699.

A freedom of information summary containing approved product labeling may be seen in the Division of Dockets Management (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.

Dated: June 25, 2003.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 03–17440 Filed 7–9–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Notice of Approval of New Animal Drug Applications; Bacitracin; Lasalocid; Narasin; Roxarsone

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice that in 2002 it approved two original abbreviated new animal drug applications (ANADAs) for clindamycin hydrochloride oral dosage forms for dogs that were not the subject of final rules. Final rules were not published because the drug-specific section of the regulation did not require amendment.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: *lluther@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: In accordance with section 512(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(i)) and 21 CFR 514.105(a) and 514.106(a), FDA is providing notice that in 2002 it approved two original ANADAs for clindamycin hydrochloride oral dosage forms for dogs that were not the subject of final rules. Final rules were not published because 21 CFR 520.446 did not require amendment.

On June 6, 2001, FDA approved original ANADA 200–316 filed by Delmarva Laboratories, Inc., 2200 Wadebridge Rd., P.O. Box 525, Midlothian, VA 23113, for the veterinary prescription use of CLINTABS (clindamycin hydrochloride) Tablets in dogs. On June 14, 2002, FDA approved original ANADA 200–298 filed by Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457, for the veterinary prescription use of

Clindamycin Hydrochloride Capsules in dogs.

Both Delmarva Laboratories' CLINTABS Tablets and Phoenix Scientific's Clindamycin Hydrochloride Capsules are approved for the for treatment of soft tissue infections (wounds and abscesses), dental infections, and osteomyelitis caused by susceptible strains of *Staphylococcus aureus*, soft tissue infections (deep wounds and abscesses), dental infections, and osteomyelitis caused by or associated with susceptible strains of *Bacteroides fragilis*, *Bacteroides melaninogenicus*, *Fusobacterium necrophorum*, and *Clostridium perfringens* as generic copies of Pharmacia & Upjohn's ANTIROBE Capsules, approved under NADA 120–161. The necessary amendments adding these sponsors' drug label codes to 21 CFR 520.446 were made in a final rule (67 FR 54954, August 27, 2002) for the approval of an unrelated supplemental NADA for the pioneer product.

Freedom of information summaries containing approved product labeling may be seen in the Division of Dockets Management (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.

Dated: June 25, 2003.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 03–17438 Filed 7–9–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0232]

Universal Reagents, Inc.; Opportunity for Hearing on a Proposal to Revoke U.S. License No. 0887

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for hearing on a proposal to revoke the biologics license (U.S. License No. 0887) issued to Universal Reagents, Inc. (URI), for the manufacture of Source Plasma. The proposed revocation is based on the failure of the establishment and the product for which the license has been issued to conform to the applicable standards established in the license and in the regulations.

DATES: URI may submit a written or electronic request for a hearing to the Division of Dockets Management by August 11, 2003, and any data and information justifying a hearing by September 8, 2003. Other interested persons may submit written or electronic comments on the proposed revocation to the Division of Dockets Management by September 8, 2003.

ADDRESSES: Submit written requests for a hearing, any data and information justifying a hearing, and any written comments on the proposed revocation to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic requests or comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: FDA is initiating proceedings to revoke the biologics license (U.S. License No. 0887) issued to URI, 2858 North Pennsylvania St., Indianapolis, IN 46202, for the manufacture of Source Plasma. The proposed revocation is based on the failure of URI to conform to the applicable standards established in its license and certain requirements of subchapter F, parts 600 to 640 (21 CFR parts 600 to 640).

I. Findings

FDA inspected URI between May 29 and June 3, 2002. Additionally, on June 7, 2002, FDA inspected Central Indiana Regional Blood Center, Inc. (CIRBC), Indianapolis, IN, which performs infectious disease testing for URI under a contract agreement. FDA determined, through its investigation and inspections of both URI and CIRBC, that URI had significant deviations from the standards established in its license as well as in the applicable Federal regulations. FDA also documented that URI has willfully engaged in violative recordkeeping practices and falsified records it submitted to FDA. The deviations noted during the inspections included, but were not limited to, the following:

1. In violation of §§ 610.40(a) and 606.160(b)(2)(i), test results for Source Plasma units 0730900, 0730911, and 0730912 for the hepatitis B surface antigen (HBsAg) and the antibody to the human immunodeficiency virus types 1 and 2 (anti-HIV–1/2) were missing from the Transfer PC Mainframe Unit Rejection Report (a computer generated report). On June 3, 2002, URI provided the FDA investigator with what URI identified as the missing test results. According to these results, the HBsAg and anti-HIV–1/2 tests, which purportedly were performed by CIRBC, were negative for Source Plasma units 0730900, 0730911, and 0730912. However, the document did not bear a date or time in the designated reporting fields. Contrary to the documents obtained at the URI inspection, FDA's inspection of CIRBC disclosed that the required testing for HBsAg and anti-HIV–1/2 was not completed or performed for these Source Plasma units.

2. In violation of §§ 610.40(a) and 606.160(b)(2)(i), HBsAg and anti-HIV–1/2 test results for Source Plasma unit 0729859 were missing on a Transfer Report and on a Testing Status Report. An additional notation on the Testing Status Report stated ''sample too old to complete testing.'' An additional record that FDA collected during the URI inspection, a Laboratory Request Form dated June 4, 2001, that URI generated, showed that all test results for unit 0729859, including HBsAg and anti-HIV–1/2 testing, were documented as ''NR'' or nonreactive. During the closeout discussion on June 3, 2002, URI provided the FDA investigator with a Testing Status Report stating that the testing had been performed at CIRBC and that test results for HBsAg and anti-HIV–1/2 were ''N'' or negative for unit 0729859. Contrary to the documents obtained at the URI inspection, FDA's inspection of CIRBC disclosed that infectious disease testing for HBsAg and anti-HIV–1/2 was not performed on Source Plasma unit 0729859.

3. In violation of § 606.160(b)(2)(i), URI failed to maintain anti-HIV–1/2 re-testing results for Source Plasma unit 0729718. On a Transfer Report dated May 5, 2001, Source Plasma unit 0729718 tested reactive for anti-HIV–1/2 in testing conducted by CIRBC. Rather than producing the results of re-testing on that unit, however, URI provided the FDA investigator, during the closeout discussion on June 3, 2002, with a Testing Status Report for unit 0729718 that noted an ''N'' or ''nonreactive'' test result for the initial anti-HIV–1/2 test. No date or time was documented on the report; however, a notation on the report stated that it was reviewed by URI on May 9, 2000 [sic]. The sequence number noted on the report was 7899. FDA's inspection of CIRBC disclosed that all infectious disease testing related to anti-HIV–1/2 that CIRBC performed on unit 0729718 in 2001 was associated with sequence number 1995, not 7899. CIRBC's records showed that anti-HIV–