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