

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹—Continued

21 CFR Section	Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1030.10(c)(4)		41	1.61	66	20	1,320
1030.10(c)(5)(i) through (c)(5)(iv)		41	1.61	66	20	1,320
1030.10(c)(6)(iii) and (c)(6)(iv)		1	1	1	1	1
1040.10(a)(3)(i)		83	1	83	3	249
1040.10(h)(1)(i) through (h)(1)(vi)		805	1	805	8	6,440
1040.10(h)(2)(i) and (h)(2)(ii)		100	1	100	8	800
1040.11(a)(2)		190	1	190	10	1,900
1040.11(c)	FDA 3147	53	2.2	115	0.5	58
1040.20 (d), (e)(1), and (e)(2)		110	1	110	10	1,100
1040.30(c)(1)		1	1	1	1	1
1040.30(c)(2)		7	1	7	1	7
1050.10(f)(1) through (f)(2)(iii)		10	1	10	56	560
Total Annual Reporting Burden						89,278

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
1002.30 and 1002.31(a)	1,150	1,655.5	1,903,825	198.7	228,505
1002.40 and 1002.41	2,950	49.2	145,140	2.4	7,080
1020.30(g)(2)	22	1	22	0.5	11
1040.10(a)(3)(ii)	83	1	83	1.0	83
Totals					235,679

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

The burden estimates were derived by consultation with FDA and industry personnel and actual data collected from industry over the past 3 years. An evaluation of the type and scope of information requested was also used to derive some time estimates. For example, disclosure information primarily requires time only to update and maintain existing manuals. Initial development of manuals has been performed except for new firms entering the industry. When information is generally provided to users, assemblers, or dealers in the same manual, they have been grouped together in table 1 of this document.

The following information collection requirements are not subject to review by OMB because they do not constitute a "collection of information" under the PRA: Sections 1002.31(c); 1003.10(a), (b), and (c); 1003.11(a)(3) and (b);

1003.20(a) through (h); 1003.21(a) through (d); 1003.22(a) and (b); 1003.30(a) and (b); 1003.31(a) and (b); 1004.2(a) through (i); 1004.3(a) through (i); 1004.4(a) through (h); and 1005.21(a) through (c). These requirements "apply to the collection of information during the conduct of general investigations or audits" (5 CFR 1320.4(b)). According to 5 CFR 1320.3(c)(2), the following labeling requirements are also not subject to review under the PRA because they are a public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public: Sections 1020.10(c)(4), 1030.10(c)(6), 1040.10(g), 1040.30(c)(1), and 1050.10(d)(1).

Dated: September 30, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–25304 Filed 10–6–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0324]

Certain Antibiotic New Animal Drug Products and Use Combinations Subject to Listings in the New Animal Drug Regulations; Drug Efficacy Study Implementation; Notice of Opportunity for Hearing; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice of opportunity for hearing that published in the **Federal Register** on August 8, 2003 (68 FR 47332). FDA is correcting a product name used by the current sponsor of NADA 141-137, the FR citation for a Drug Efficacy Study Implementation Program finding of effectiveness, and the column headings of six tables. These corrections are being made to improve the accuracy of the **Federal Register**. This notice also extends the deadline for parties who have requested a hearing to submit data and analysis upon which their request for a hearing relies. Other interested persons may submit comments on the notice of opportunity for hearing (NOOH) before the deadline.

DATES: Submit all written data and analysis upon which a request for a hearing relies and other written comments by November 6, 2003.

FOR FURTHER INFORMATION CONTACT: Andrew J. Beaulieu, Center for Veterinary Medicine (HFV-1), 7519 Standish Pl., Rockville, MD 20855, 301-827-2954, e-mail: abeaulie@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 8, 2003 (68 FR 47332), FDA announced the effective conditions of use for some of the drug products and use combinations subject to the listings in §§ 510.515 and/or 558.15 (21 CFR 510.515 and/or 558.15), and proposed to withdraw the new animal drug applications (NADAs) for those products or use combinations lacking substantial evidence of effectiveness following a 90-day opportunity to supplement the NADAs with labeling conforming to the relevant findings of effectiveness. The Center for Veterinary Medicine (CVM) also provided an opportunity for hearing for applications proposed to be withdrawn. Interested persons were given until September 8, 2003, to submit written appearances and requests for a hearing; until October 7, 2003, to submit data and analysis upon which a request for a hearing relies; and until November 6, 2003, to submit supplemental NADAs. After publication of the NOOH, several errors were found by CVM and others. CVM is correcting these errors, but does not believe that these corrections alter the underlying basis of the NOOH.

II. Corrections

In FR Doc. 03-20241, published August 8, 2003 (68 FR 47332), the following corrections are made:

1. On page 47333, in the third column, under “*A. Bacitracin Methylene Disalicylate Single-Ingredient Type A Medicated Articles*,” the trade name following NADA 141-137, “FORTRACIN,” is corrected to read “PENNITRACIN”.

2. On pages 47335 in tables 2, 3, and 4, and on page 47336 in table 5, in the table heading “Oxytetracycline” is corrected to read “Oxytetracycline¹” with a footnote added to read “¹Expressed in terms of an equivalent amount of oxytetracycline hydrochloride” and “Neomycin” is corrected to read “Neomycin Sulfate”.

3. On pages 47335 in tables 2, 3, and 4, and on page 47336 in table 5 in the first column heading “Oxytetracycline” is corrected to read “Oxytetracycline¹” and “neomycin” is corrected to read “neomycin sulfate”.

4. On page 47336, in the first column, under “*C. Combination Drug Type B and Type C Medicated Feeds for Poultry Containing Nicarbazine*,” the combination use following NADA 98-371 “NICARBAZIN (nicarbazine), PENICILLIN G PROCAINE (procaine penicillin), and 3-NITRO (roxarsone)” is corrected to read “nicarbazine, procaine penicillin, and roxarsone”.

5. On page 47336, in the first column, under “*C. Combination Drug Type B and Type C Medicated Feeds for Poultry Containing Nicarbazine*,” the combination use following NADA 98-374 “NICARBAZIN (nicarbazine) and PENICILLIN G PROCAINE (procaine penicillin)” is corrected to read “nicarbazine and procaine penicillin”.

6. On page 47336, in the second column, under “*C. Combination Drug Type B and Type C Medicated Feeds for Poultry Containing Nicarbazine*,” the combination use following NADA 100-853 “NICARBAZIN (nicarbazine), BACIFERM (BMD), and 3-NITRO (roxarsone)” is corrected to read “nicarbazine, bacitracin methylene disalicylate, and roxarsone”.

7. On page 47336, in the third column, under “*C. Combination Drug Type B and Type C Medicated Feeds for Poultry Containing Nicarbazine*,” in the fourth line, “bacitracin zinc” is corrected to read “bacitracin methylene disalicylate”.

8. On page 47336, in the third column, in the eighth and ninth lines, “35 FR 12490, August 5, 1970 (bacitracin zinc)” is corrected to read “35 FR 11531, July 17, 1970, as corrected by 35 FR 15408, October 2, 1970 (bacitracin methylene disalicylate)”.

9. On page 47337 in table 6, and on page 47338 in table 7, in the first three column headings “Type A article in g/

ton” is corrected to read “Drug in g/ton”.

Dated: October 1, 2003.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 03-25343 Filed 10-6-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies Federal agencies of the laboratories currently certified to meet the standards of Subpart C of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines) published in the **Federal Register** on April 11, 1988 (53 FR 11970), and revised in the **Federal Register** on June 9, 1994 (59 FR 29908) and on September 30, 1997 (62 FR 51118). A notice listing all currently certified laboratories is published in the **Federal Register** during the first week of each month. If any laboratory's certification is suspended or revoked, the laboratory will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory has withdrawn from HHS' National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end, and will be omitted from the monthly listing thereafter.

This notice is also available on the Internet at <http://workplace.samhsa.gov> and <http://www.drugfreeworkplace.gov>

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersch or Dr. Walter Vogl, Division of Workplace Programs, 5600 Fishers Lane, Rockwall 2, Room 815, Rockville, Maryland 20857; 301-443-6014 (voice), 301-443-3031 (fax).

SUPPLEMENTARY INFORMATION: The Mandatory Guidelines were developed in accordance with Executive Order 12564 and section 503 of Public Law 100-71. Subpart C of the Guidelines, “Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies,” sets strict standards that laboratories must meet in order to