

RECORDS AND REPORTS CONCERNING EXPERIENCE WITH APPROVED NEW ANIMAL DRUGS—Continued
TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section/Title/FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
514.80(b)(5)(ii)/Advertising and Promotional Materials Report/ Form FDA 2301	190	2.11	772	2	1,544
514.80(b)(5)(iii)/Distributor's Statement Report/ Form FDA 2301	530	0.14	56	2	112
Total					35,177

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

² The reporting burden for § 514.80(b)(4)(iv)(A) is included in the reporting burden for § 514.80(b)(2)(i).

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency of Response	Total Annual Responses	Hours per Response	Total Hours
514.80(e) ²	530	28.22	19,385	0.5	9,693
514.80(e) ³	530	4.06	2,379	10.35	24,623
Total					34,316

¹ Burden estimates were separated between Form FDA 1932 and Form FDA 2301 to reflect the difference in estimates for "Hours per Respondent" required.

² Recordkeeping estimates for § 514.80(b)(1), (b)(2)(i), (b)(2)(ii), and (b)(3); Form FDA 1932.

³ Recordkeeping estimates for § 514.80(b)(2)(iii), (b)(4), (b)(5), and (c); Form FDA 2301.

Forms FDA 1932 and FDA 2301 for this collection of information are currently approved under OMB control number 0910-0012 and will not change due to implementation of this regulation. The reporting and recordkeeping burden estimates in this document are based on the submission of reports to the Division of Surveillance, CVM. The total annual response numbers are based on the 2000 fiscal year submission of reports to the Division of Surveillance, CVM. The numbers in tables 1 and 2 of this document are total burden associated with this regulation. Section 514.80(b)(3) and (b)(4)(v) are new information collection requirements over the current requirements.

The information collection provisions of this final rule have been submitted to OMB for review. FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

List of Subjects

21 CFR Part 211

Drugs, Labeling, Laboratories, Packaging and containers, Prescription

drugs, Reporting and recordkeeping requirements, Warehouses.

21 CFR Part 226

Animal drugs, Animal feeds, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

21 CFR Part 510

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

21 CFR Part 514

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 211, 226, 510, and 514 are amended as follows:

PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

■ 1. The authority citation for 21 CFR part 211 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 360b, 371, 374.

§ 211.198 [Amended]

■ 2. Section 211.198 *Complaint files* is amended in paragraph (a) in the last sen-

tence by removing "in accordance with § 310.305 of this chapter" and adding in its place "in accordance with §§ 310.305 and 514.80 of this chapter."

PART 226—CURRENT GOOD MANUFACTURING PRACTICE FOR TYPE A MEDICATED ARTICLES

■ 3. The authority citation for 21 CFR part 226 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360b, 371, 374.

■ 4. Section 226.1 is amended by redesignating the existing text as paragraph (a) and by adding paragraph (b) to read as follows:

§ 226.1 Current good manufacturing practice.

* * * * *

(b) In addition to maintaining records and reports required in this part, Type A medicated articles requiring approved NADAs are subject to the requirements of § 514.80 of this chapter.

PART 510—NEW ANIMAL DRUGS

■ 5. 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.

§ 510.300 [Removed]

■ 6. Section 510.300 *Records and reports concerning experience with new animal drugs for which an approved application is in effect* is removed.