

reviewing each collection of information.

Title: Records and Reports Concerning Experience With Approved New Animal Drugs.

Description: This final rule amends the provisions of the animal drug regulations concerning requirements for recordkeeping and reports concerning experience with approved new animal drugs. The information contained in the reports required by this rule enables FDA to monitor the use of new animal drugs after approval and to ensure their continued safety and efficacy. The reporting requirements include: A report that provides information on product and manufacturing defects that may result in serious adverse drug events within 3 days of becoming aware the defect exists (new § 514.80(b)(1)); a report that provides information on serious and unexpected adverse drug events and a followup report on such events (new § 514.80(b)(2)); a summary report of increased frequency of ADEs (new § 514.80(b)(4)(v)); a report from nonapplicants, such as distributors, to applicants providing information on ADEs (new § 514.80(b)(3)); a periodic report with information on distribution, labeling, manufacturing or controls changes, new laboratory studies, and all adverse events in the reporting period (new § 514.80(b)(4)); and other reports that include special drug experience reports; reports for advertising and promotional labeling, and reports for distributor statements (new § 514.80(b)(5)). These reports must be kept for 5 years (new § 514.80(e)).

The final rule strengthens the current reporting system by requiring periodic

reports every 6 months for the first 2 years following initial approval of an application rather than just for the first year following initial approval. The increased burden on applicants amounts to one additional periodic report. While greater than the reporting burden in the previous rule, this burden is less than that of the proposed rule which would have required quarterly periodic reports for 3 years following initial approval.

All periodic reports must be submitted with Form FDA 2301, "Transmittal of Periodic Reports and Promotional Materials for New Animal Drugs" (OMB control number 0910-0012). ADE reports must be submitted on Form FDA 1932, "Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report" (OMB control number 0910-0012).

In the **Federal Register** of February 4, 2002, FDA invited comments on the interim final rule and the information collection requirements. Only one comment received pertained to information collection. That comment stated that the requirements under "Multiple Applications" do not appear to decrease but may increase the burden on the applicant. In particular, the comment questioned the requirement under § 514.80(c)(4) and requested clarification. The comment also voiced concern about an increased reporting burden due to the increasing number of approved applications for combinations of drugs for use in feeds since the implementation of the ADAA. Further complicating the reporting issue is that frequently there are nonapplicants involved in the marketing of these combinations. The comment stated that

with the exception of "promotion literature," there is rarely any other information to be reported, suggesting that the "promotion literature" be submitted to the application held by either party, i.e., the nonapplicants or applicant, and not the application approved for the use of the combination of drugs.

In response, FDA notes that the provision of the regulation in question is currently codified under § 510.300(b)(4)(ii). The current regulation and the proposal in the interim final rule are similar. There is no increase of the reporting burden. It is not the intention of FDA for the implementation of § 514.80(c) to be different than the current requirement under § 510.300(b)(4)(ii). Only information specific to a particular NADA/ANADA that is not common to all the applications must be included in the report for that particular NADA/ANADA, for example, labeling. With regard to the comment that there is an increased reporting burden due to the ADAA, increased reporting is due to the increased number of approved applications, and not due to different requirements. FDA consequently believes that this is a reasonable reporting requirement.

Description of Respondents: Applicant respondents are sponsors of approved NADAs and ANADAs. Nonapplicant respondents are those, other than the applicant, involved in manufacturing, processing, packing, labeling, or distributing new animal drugs.

RECORDS AND REPORTS CONCERNING EXPERIENCE WITH APPROVED NEW ANIMAL DRUGS

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)(2)(i)/Original 15-Day Alert Report/Form FDA 1932	190	55.26	12,283	1	12,283
514.80(b)(1)/3-Day Field Alert Report/ Form FDA 1932	190	0.32	95	1	95
514.80(b)(2)(ii)/Followup 15-Day Alert Report/Form FDA 1932	190	17.90	6,007	1	6,007
514.80(b)(3)/Nonapplicant Report/ Form FDA 1932	340	2.94	1,000	1	1,000
514.80(b)(4)/Periodic Drug Experience Report/Form FDA 2301, and 514.80(c) Multiple Applications ²	190	7.11	1,226	11	13,486
514.80(b)(4)(v)/Summary Report of Increased Frequency of Adverse Drug Experience	190	1.58	300	2	600
514.80(b)(5)(i)/Special Drug Experience Report/ Form FDA 2301	190	0.13	25	2	50