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SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Records and Reports Concerning Experience With Approved New Animal Drugs— (OMB Control Number 0910-0284)

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: (1) 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 (§ 514.80(b)(1) (21 CFR 514.80(b)(1))); (2) a report that provides information on serious and unexpected adverse drug events and a followup report on such events (§ 514.80(b)(2)); (3) a summary report of increased frequency of adverse drug experiences (§ 514.80(b)(4)(v)); (4) a report from nonapplicants, such as distributors, to applicants providing information on adverse drug experiences (§ 514.80(b)(3)); (5) a periodic report with information on distribution, labeling, manufacturing or controls changes, new laboratory studies, and all adverse events in the reporting period (§ 514.80(b)(4)); (6) other reports that

include special drug experience reports; and (7) reports for advertising and promotional labeling, and reports for distributor statements (§ 514.80(b)(5)). These reports must be kept for 5 years (§ 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). Adverse drug experience 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 (67 FR 5046), 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 Animal Drug Availability Act of 1996. 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 from the current requirement under § 510.300(b)(4)(ii). There is no additional reporting burden than that already covered under § 514.80(b)(4). Section 514.80(c) is not an additional information collection, i.e., in addition to § 514.80(b)(4); it is an administrative tool for industry to use to submit common information only once to FDA. Only information specific to a particular new animal drug application (NADA)/ abbreviated new animal drug application (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 Animal Drug Availability Act of 1996, increased reporting is due to the increased number of approved applications. 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.

FDA estimates the burden of this collection of information as follows:

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