

implementation of § 514.80(c) to be different from 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.

U. Records to Be Maintained and Access to Records and Reports (§ 514.80(e) and (f))

(Comment 29) One comment asked where the primary repository for foreign report records (United States versus the foreign country) would reside.

Sponsors should keep records wherever it is their customary business practice to keep them as long as the records are available to FDA for inspection.

V. General Comments on the Regulation

(Comment 30) One comment requested that CVM adopt procedures for waiving the reporting of ADEs for NADAs/ANADAs. The comment suggested adopting procedures similar to FDA's Center for Drug Evaluation and Research's March 2001 draft publication entitled "Guidance for Industry on Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines." This guidance states that applicants under certain conditions may request waivers from submission of full ADE reports that are both nonserious and labeled.

We disagree with the comment. The procedures in the draft guidance cited by the commenter only waive reporting such adverse experiences on FDA Form 3500A. The applicant still must collect and report these adverse experiences by providing a summary tabulation by body system and a narrative discussion about all adverse experiences in the periodic report. FDA also may request that the applicant submit these reports on the human form (FDA Form 3500A) within 5 calendar days after receipt of the agency's request. The final records and reports rule does not include such a summary tabulation or narrative discussion requirement. We believe that adding such a requirement would impose a greater burden on the regulated industry than the requirement of reporting such adverse events on Form FDA 1932 in periodic reports. Further, we believe it is crucial that all

adverse drug experience information be submitted in a consistent manner and format to facilitate the agency's analysis of the information. For these reasons, we have not adopted the change proposed by this comment.

(Comment 31) One comment asked if ADEs and product defects for unapproved products, which meet the requirements of 21 CFR part 801(e)(1) of the act, should be reported.

No, this regulation only pertains to approved new animal drugs.

(Comment 32) One comment asked if a validated electronic signature in compliance with part 11 (21 CFR part 11) would suffice for an authorized signature on Form FDA 1932.

Yes, an electronic signature that is compliant with part 11 will be acceptable.

(Comment 33) One comment apparently has misinterpreted the table that outlines the purpose of each paragraph. In particular, the comment indicated belief that the purpose given for § 514.80(b)(1) also pertained to the next line § 514.80(b)(2).

FDA believes that the commenter has simply misinterpreted the table. Section 514.80(b)(1) and (b)(2) are separate line items in the table. The confusion appears to be because the purpose column for § 514.80(b)(2) is blank because the subsequent three titles are subsections of § 514.80(b)(2), i.e., § 514.80(b)(2)(i) through (b)(2)(iii). Thus, a blank in the purpose column does not mean the preceding description applies. For clarity's sake, however, FDA has added the phrase "See paragraphs below" in place of the blank spaces.

III. Summary of the Final Rule

FDA is withdrawing the interim final rule on its requirements for records and reports concerning experiences with approved new animal drugs (67 FR 5046) and is issuing this final rule. This final rule represents a modification of the withdrawn interim final rules. The modifications in the final rule include: Revising the definitions of "applicant" and "serious adverse drug experience;" modifying the reporting requirement for summary reports of increased frequency of ADEs; clarifying what safety and efficacy records a nonapplicant versus an applicant must maintain; eliminating the requirement of submission of prepublication manuscripts relating to completed clinical trials; changing distributor's labeling so that the qualifying phrase that must precede the name and address of the distributor is as permitted by § 201.1; and revising the section of the rule pertaining to distributor's signed statements to state that the distributor will promote the

product only for use under the conditions stated in the approved labeling.

IV. Conforming Changes

With the amendment of the animal drug regulations, certain revisions to parts 226, 510, and 514 (21 CFR parts 226, 510, and 514) and 21 CFR part 211 are required to conform to the designations in the amendments. Certain other provisions of part 510 and § 514.8 are superseded by these regulations and are removed.

V. Environmental Impact

FDA has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

VII. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612) and the Unfunded Mandates Reform Act (Public Law 104–4). The Office of Management and Budget (OMB) has determined that this final rule is a significant regulatory action subject to review under Executive Order 12866. FDA also certifies in accordance with the Regulatory Flexibility Act that this rule will not have a significant economic impact on a substantial number of small entities, and therefore, a regulatory flexibility analysis is not required. Further, the Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for the final rule because it is not expected to result in any 1-year expenditure that would exceed \$100 million adjusted for inflation. The