

current inflation-adjusted statutory threshold is about \$110 million.

The regulation is intended to clarify and simplify recordkeeping requirements while improving the protection of public and animal health. The revisions in the reporting requirements are expected to provide savings through lower recordkeeping costs in some areas while imposing small cost increases due to requirements for recordkeeping of more useful information.

In the rule, the term "applicant" is limited to the holder of an approved application (NADA or ANADA) and does not include every firm whose name appears on product labeling, as the regulations previously provided. A nonapplicant is required to send copies of necessary information to the applicant who would then combine all information received, whether from one or several sources, and submit a single report to FDA. This change would reduce paperwork requirements because firms would be required to submit fewer reports. Also, those reports should provide for a more comprehensive reporting of all required information.

The current requirement for ADE reports to be submitted by distributors is retained under the final rule in § 514.80(b)(3) in nonapplicant reporting. The requirement for any firm involved in the manufacturing, processing, packing, labeling, or distributing of a new animal drug product other than the applicant (the nonapplicant) to report adverse experiences either to FDA or to the applicant is a restatement of the previous provisions of § 510.300(f) that applies to a small number of firms that would not routinely be expected to receive such information. The restatement is intended to clearly state that any such information received is required to be reported to FDA, either directly or through the applicant. However, only one party would be required to file the report.

The revised regulations amend the language of the regulations to clarify current practices. The conformity of reporting requirements for animal drugs and human drugs may simplify the process for firms that manufacture both kinds of products. No added costs are expected for those firms that only manufacture new animal drug products. In the past, FDA has required that records and reports be retained for an indefinite period. The proposed rule provided for a retention period of 10 years. In response to industry comments, FDA changed this requirement in the interim final rule to 5 years for all information. This would provide an additional opportunity for

savings compared to the proposed rule. No additional comments were received on this issue, and the 5-year retention period has been retained in the final rule. Since the current average length of time which records are kept is unknown, it is possible that there will be a small net cost due to this provision, even though the reporting requirements are clarified for easier compliance and administration.

The previously existing regulation required reports concerning newly approved NADAs and ANADAs every 6 months for the first year and annually thereafter. The proposed rule for records and reports would have required submission of such reports at quarterly intervals for 3 years following approval. FDA agrees with comments from industry that the proposed rule's requirement of reports at quarterly intervals for 3 years following approval was unnecessary, and the agency decreased the reporting requirements in the interim final rule. No additional comments were received on this issue. The final rule requires reports of ADEs to be submitted every 6 months for 2 years and annually thereafter.

The net change from the previous regulation requires one additional report in the second year. FDA estimates that it approves 30 NADAs annually. FDA estimates that 13.6 hours are required to establish and maintain the drug experience data, as well as write the report. Total hours required for this provision are estimated at 408. At a middle manager's estimated total wage rate of about \$35 per hour, this provision would cost \$14,280 annually. Moreover, applicants may petition for lengthier report intervals. FDA will provide for reporting at intervals longer than 1 year when justified based on current experience or manufacturing and marketing status. The expected number of petitions for reporting at intervals greater than 1 year is difficult to estimate because it depends on the extent to which each individual company wishes to qualify for this provision. The net result of these two provisions may be either a very small cost or savings to each firm.

The interim final rule would have required applicants to periodically review the incidence of ADEs and report any significant increase in the frequency to FDA as soon as possible or within 15 working days of determining a significant increase in frequency exists. In response to comments, the final rule provides more flexibility to industry by allowing these reports to be submitted in the periodic drug experience reports rather than within the 15-day period. FDA expects to receive very few of these

reports each year and estimates that the annual number will be between 1 and 20. These reports would not be expected to take more than 1 to 2 hours of a manager's time, and the high-end estimated cost to industry would be \$1,400 annually. Periodic review of ADE reports, although on a less formal basis, is currently understood to be normal business practice.

The net costs and benefits of this final rule, though indeterminate, are expected to be modest. FDA concludes that the impacts of the final rule do not qualify it as an economically significant rule as defined under Executive Order 12866.

The Regulatory Flexibility Act, as amended (5 U.S.C. 601–612), allows for a waiver of the regulatory flexibility analysis if an agency certifies there will not be a significant impact on a substantial number of small entities as a result of a rule, as well as provides the factual basis for such a certification. The Small Business Administration definition of a small business in this industry category is limited to those firms with less than 750 employees. It is expected that a substantial number of the firms that will be subject to the new recordkeeping and reporting requirements will meet the definition of small businesses. FDA estimates that from 1 to 13 of the approximately 30 NADA and ANADA approvals in 1999 may have been from small businesses. Using the upper end of this range, about 42 percent of the firms receiving approval annually would be subject to the new recordkeeping and reporting requirements. This regulation is not expected to have a significant economic impact on these firms because the final rule is intended to simplify and clarify current recordkeeping and reporting requirements. The net costs and benefits on each small firm are expected to be modest. Accordingly, FDA certifies in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612) that this rule will not have a significant economic impact on a substantial number of small entities. A regulatory flexibility analysis, therefore, is not required.

VIII. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). A description of these provisions is given below. Included is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and