

and 0910-0353), 606 (approved under OMB control number 0910-0116), and 820 (21 CFR part 820) (approved under OMB control number 0910-0073) and, therefore, are not included in the burden calculation for the separate requirement of submitting a deviation report to FDA.

In the **Federal Register** of June 30, 2003 (68 FR 38712), FDA published a 60-day notice requesting public comment on the information collection provisions. We received two comments.

In response to whether the proposed collection of information is necessary, comment one stated that we should harmonize the biological product deviation reporting requirements (§ 600.14) with the NDA field alert reports under 21 CFR 314.81(b)(1) and, therefore, revoke § 600.14. The comment stated the adoption of the new drug application (NDA) field alert regulations for all biologics would streamline compliance activities, and facilitate and align the recent transfer of biotechnology products from CBER to the Center for Drug Evaluation and Research (CDER). The comment also stated that revocation of § 600.14 would reduce the reporting burden while continuing to support the industry in making good, risk based quality decisions.

The NDA field alert regulations (approved under OMB control number 0910-0001) are applicable only to those products that are approved for marketing under the provisions of part 314 (21 CFR part 314) (including those few products that CBER regulates even though they were approved under the NDA provisions of part 314). The NDA field alert regulations do not apply to biological drug products subject to licensing under the Public Health Service (PHS) Act, including licensed products that CDER now regulates. FDA has harmonized a number of regulations for certain biotechnology products where products regulated as biological products subject to licensure are similar to products subject to regulation as new drugs (see 65 FR 66621 at 66625, November 7, 2000). The products recently transferred from CBER to CDER are still regulated as biological products under the PHS Act. However, we recently stated in our CBER Web site that the biological product deviation reports for those transferred products are now to be sent to CDER. CBER will continue to monitor and assess its biological product deviation reporting program. If the level of reporting or the needs of the agency change, FDA will consider whether to harmonize its reporting requirements. The comment's suggestion that FDA adopt the NDA

field alert regulations in § 314.81(b)(1) and revoke § 600.14 seeks a regulatory change that is outside the scope of FDA's current request for OMB renewal of the information collection in the existing regulations. Consequently, we decline to adopt the comment's recommendations.

Comment two, in response to the necessity of the proposed regulation, recommended revisions to the regulation regarding the submission of reports regarding post-donation information, and argued that only a small percentage of those reports were forwarded to District Offices for further investigation and that the reporting burden has resulted in little tangible outcome. FDA uses those reports for reasons other than initiating further investigation or product recalls. For example, some reports of post-donation information revealed to FDA that the manufacturers had flaws in their donor screening procedures, which FDA communicated to the companies. In addition, information from biological product deviation reports has been valuable to FDA in crafting guidances for industry that improve product quality and reduce manufacturing problems generally. However, we will continue to monitor and assess our biological product deviation reporting program, including the review of these type of reports. Consequently, we decline to adopt the comment's recommendations at this time.

In response to FDA's burden estimate, comment one questioned the estimated hours per response to submit a report to FDA and stated that FDA's estimate did not factor in the time to completely process the report. The comment provided an estimation of burden hours to submit a report 10 times FDA's estimate. In addition, the comment stated that additional time is required to update SOPs associated with the regulation and to perform ongoing training.

Based on comments received in response to the burden hours published in the proposed rule of September 23, 1997 (62 FR 49642), FDA revised the burden hours (hours per response) in the final rule (65 FR 66621 at 66632, November 7, 2000) to the current estimate. In response to the comments on the proposed rule, we stated the revised estimate was based in part on information from industry representatives about typical procedures, and the availability of a standardized report form. Activities such as investigating, changing SOPs or processes, and followup are required under parts 211, 606, and 820, and therefore, are not included in the

burden estimate for the separate requirement of submitting to FDA a biological product deviation report. In the final rule, we estimated the hours as a one-time burden, in part, for establishing and making adjustments to SOPs and staff training. Continuance of these activities would be considered as part of normal business practice or covered by other regulations. We, therefore, decline to revise the burden hours.

Comment two questioned FDA's estimate that the rate of submissions was not expected to change significantly in the next few years. The comment stated that there was a large increase in the number of reports from the previous year.

We realize that the number of reports increased in the first couple of years after issuance of the final rule as industry adjusted to the new reporting requirements. However, we expect the numbers of reports to level off after this adjustment period, and therefore, we estimate that the rate of submission will not significantly increase in the next few years. If the number of reports significantly increases unexpectedly in the next few years, we will adjust the estimates at the next interval for approval of the information collection. Consequently, we decline to revise the estimates at this time.

In response to ways of minimizing the collection burden, comment one stated that we should notify manufacturers when a report is submitted that is not deemed to meet the threshold for reporting. The comment also stated that firms are not comfortable with filing submissions electronically because there are inadequate safeguards to ensure against false reports.

For reports submitted electronically, we notify the manufacturer of those reports that do not meet the threshold for reporting. For those submitted in hard copy, we notify the manufacturer if a trend of a particular type of unnecessary report is detected. We currently have an approximate rate of 45 percent of reports submitted electronically with the majority being submitted by the blood industry. Because the system is designed with a user name and password that is associated with the establishment, we believe there are adequate safeguards for submitting the information electronically.

Comment two responded to ways of minimizing the collection burden by recommending that post-donation information be reported in summary format not to exceed annually. Although, as mentioned previously, FDA has made valuable use of