



Date: APR 26 2002

Dockets Management Branch  
(HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

4331 02 APR 29 19 56

Re: Docket Number 02N-0012, OC 20026  
Response to FDA Call for Comments  
Agency Information Collection Activities; Proposed Collection; Comment Request  
Postmarketing Adverse Drug Experience Reporting

Dear Sir or Madam:

Reference is made to the February 25, 2002 (Volume 67, Number 37) Federal Register notice soliciting comments on postmarketing adverse drug experience reporting and recordkeeping requirements.

AstraZeneca has reviewed this document and our comments are attached.

Please direct any questions or requests for additional information to Janet Steiner, Director of Safety Strategy, at 302-885-1265.

Sincerely,

Roberta J. Sullivan  
Director, Business Improvement and Strategic Planning  
Regulatory Affairs  
302-886-2823

JS/kc

Enclosure

02N-0012

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US Regulatory Affairs  
AstraZeneca Pharmaceuticals LP  
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Docket No. 02N-0012 –  
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**AstraZeneca Comments:**

Comment 1:

While we would agree that the proposed collection of information is necessary for the proper performance of FDA's functions, and that the collection of adverse event information is essential to monitoring the safety of marketed products, we believe the efficiency of this information collection could be improved, with corresponding increases in information quality and practical value. Suggestions for improvements are described under Comments 3 and 4 below.

Comment 2:

While this document does not indicate what methods and assumptions were used by FDA to calculate either the annual reporting burden, or the annual record keeping burden of the proposed collection of information, the low numbers of the estimates provided would seem to reflect only the FDA's effort, and not that of the respondents.

The annual number of responses (number of Periodic Reports prepared) per respondent is significantly underestimated. For example, AstraZeneca submits over 70 Periodic Reports (annual and quarterly reports) every year.

Likewise, the hours for preparing Periodic Reports under 314.80(c)(2) are also grossly underestimated. On average, the preparation, quality control, and production of the NDA Periodic Reports at AstraZeneca take from 100 to 300 hours each.

All adverse drug experience reports, including non-15-Day Alert Reports, need to be taken into account when calculating the burden, as all reports received need to be assessed, processed, and reviewed for determination of appropriate classification and prioritization. For example, AstraZeneca received approximately 18,200 initial spontaneous adverse drug experience reports in association with their marketed prescription products from worldwide sources in 2001, approximately 1800 of which qualified as 15-Day Alert Reports. Additionally, approximately 700 follow-up 15-Day Alert Reports involving prescription products were submitted to FDA during the same period.

With regard to the estimated annual recordkeeping burden, we disagree with the statement that there are no capital, operating, or maintenance costs associated with maintaining records of adverse experience reports for ten years. To meet this requirement, AstraZeneca has to maintain facilities to store what amounts to tons of

Docket No. 02N-0012 –  
Agency Information Collection Activities; Proposed Collection; Comment Request;  
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paper records, in addition to back-up records on other media (scanned optical images, microfilm, etc.). Costs for storage and retrieval are substantial (e.g., thousands of dollars per year).

Comment 3:

AstraZeneca would like to suggest the following ways to enhance the quality, utility, and clarity of the information to be collected:

1. AstraZeneca urges the FDA to change their Periodic Reporting requirements to be consistent with the ICH Guidelines for Periodic Safety Update Reports as soon as possible. This will enable companies to submit the same report to all regulatory authorities globally, and will decrease the burden involved with preparing Periodic Reports specifically for FDA. Additionally, for those companies, such as AstraZeneca, who have received waivers from the Agency to submit Periodic reports in the PSUR format, adoption of ICH standards would decrease the burden of adding US-specific appendices to the reports.
2. We would also recommend that Periodic Safety Update Reports to FDA do not routinely include any information in addition to that included in the ICH Guidelines for Periodic Safety Update Reports. Specifically, FDA should not require full copies in either paper or electronic form of cases that were previously reported to the Agency (e.g., expedited reports) or cases that present little if any added value (e.g., non-serious expected reports). We feel that submission of full copies of cases with the PSUR should be restricted to serious/expected and non-serious, unexpected adverse events. If a potential signal arises about a specific product, all available information associated with any individual case(s) could be provided promptly to the FDA upon request.

Comment 4:

AstraZeneca would like to suggest the following ways to minimize the burden of the collection of information on the respondents:

1. AstraZeneca welcomes the opportunity to submit 15-Day Alert Reports by electronic transmission, as long as this method is not encumbered by requirements to submit supplementary paper items as well. For example, eliminating the requirement for submitting original literature articles as attachments to 15-Day Alert Reports would allow reports from the literature to be submitted electronically using the E2B format. Additionally, elimination of this requirement would result in significant cost savings by both FDA and respondents. Articles would always be available to FDA on request.
2. Considerable cost savings could also be realized by eliminating the requirement to collect non-serious labeled events. Collection of this type of information adds little value to protecting patient safety, and ties up valuable resources that should be focused on collection and evaluation of more medically significant cases.

Docket No. 02N-0012 –  
Agency Information Collection Activities; Proposed Collection; Comment Request;  
Postmarketing Adverse Drug Experience Reporting

3. AstraZeneca welcomes Agency efforts to consider provisions for alternate methods of data storage other than through hard copy paper records. We feel that companies should have the option to choose and maintain methods for storage and retrieval of records according to specific company needs, as long as established standards (such as those outlined in the various guidances on electronic submissions) are followed. Storing scanned optical images of records instead of paper copies would considerably decrease the need for large file rooms and extensive off-site storage facilities, and the costs associated with maintaining these facilities.