AstraZeneca

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

Dear Sir or Madam:

Re: Docket No. 01D-0185
Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format - Postmarketing Expedited Safety Reports

Reference is made to the May 4, 2001 *Federal Register* Notice announcing the availability of Draft Guidance for Industry entitled, "***Providing Regulatory Submissions in Electronic Format -- Postmarketing Expedited Safety Reports.***" AstraZeneca Pharmaceuticals LP has reviewed this guidance and our comments are attached.

Thank you for your consideration.

Sincerely,

Margaret G Melville

Margaret G. Melville
Regulatory Affairs Director
(302) 886-2118
(302) 886-2822 (fax)

MGM/OM/djr
Attachment

01D-0185

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US Regulatory Affairs
AstraZeneca Pharmaceuticals LP
1800 Concord Pike PO Box 8355 Wilmington DE 19803-8355

Comments for: Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Postmarketing Expedited Safety Reports

Docket Number: 01D-0185

Federal Register: May 4, 2001, Volume 66, Number 87, Notices, Pages 22585 - 22586

General Comments:

• This guidance only addresses postmarketing expedited safety reports. The E2b format would also be an appropriate vehicle to submit FDA Form 3500As sent in support of Periodic Adverse Drug Experience reports per 314.80 (c) (2). The Agency should consider accepting electronic submissions of FDA Form 3500As that accompany Periodic Adverse Drug Experience reports using physical media with SGML E2b files in lieu of paper FDA Form 3500As.

• The attachment process contained in this guidance is cumbersome. Could the Agency consider waiving the requirement for attached literature articles if the case narrative contains the literature reference? This proposal would simplify the cumbersome process for submission of publications in support of safety reports as well as avoid copyright issues. If this proposal were adopted, and the Agency required a copy of a referenced article, they could request a copy from the Sponsor.

• This draft guidance does not address the submission of premarketing (IND) expedited safety reports. What is the Agency's guidance to Industry with regard to the submission of a case is reportable to both an NDA and an IND? As written the guidance would result in simultaneous electronic and paper submission of the same event. It would be optimum if the Agency would agree a single standardized electronic submission process for all expedited FDA Form 3500As, both in the pre- and postmarketing setting.

- What contingencies are there in the event that the FDA gateway is inoperable? Clarification is needed for both submission and notification processes in this event.