AstraZeneca

5462 '01 FEB 2 A11 :44

February 1, 2001

Dockets Management Branch
Food and Drug Administration
HFA No. A-305, Room No. 1061
5630 Fishers Lane
Rockville, MD 20852

Dear Madam or Sir:

Re: Docket No. 00N-1545
Applications for FDA Approval to Market a New Drug;
Proposed Revision of Post-marketing Reporting Requirements

Reference is made to the November 7, 2000 ***Federal Register*** Notice announcing the availability of "Applications for FDA Approval to Market a New Drug; Proposed Revision of Post-marketing Reporting Requirements."

AstraZeneca Pharmaceuticals LP has reviewed this regulation and our comments are attached.

Thank you for your consideration.

Sincerely,

Omaira Meléndez, Pharm.D.
Regulatory Project Associate, Oncology
Regulatory Affairs
(302) 886-2762
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OM/jr
Enclosure

00N-1545

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

Docket number: 00N-1545
Applications for FDA Approval to Market a New Drug;
Proposed Revision of Post-marketing Reporting Requirements

Federal Register: November 7, 2000, Volume 65, Number 216,
Proposed Rules, Page 66665 – 66670

Section	Page No.	Line No. or Paragraph No. (if applicable)	Comment
II. Section 506c of the Act	2	Last Paragraph under No. 3	The Agency notes that a manufacturer may distribute a drug to satisfy existing market need for 6 months. Can the Agency clarify whether this 6-month period is in addition to the 6-month notice period (for a total of one year), or is this 6 months the period of the notification to withdraw? In other words, is the manufacturer in this special instance allowed 1 year of marketing after making the decision to withdraw the product?