AstraZeneca

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

RE: Docket Number 02N-0204
Response to Call for Comments
Bar Code Label Requirements for Human Drug Products and Blood

Dear Sir or Madam:

Reference is made to the March 14, 2003 Federal Register notice announcing the request for comments on Bar Code Label Requirements for Human Drug Products and Blood.

AstraZeneca has reviewed this proposed rule and our comments are attached.

Please direct any questions or requests for additional information to me, or in my absence to Kathy Powell, Labeling Associate at 302-886-2135.

Sincerely,

Carolyn Russello-Callahan
Associate Director Labeling
Regulatory Affairs

02N-0204

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Response to Call for Comments
Bar Code Label Requirements for Human Drug Products and Blood
Docket Number 02N-0204

General Comments:

- Respiratory inhalation products packaged in plastic ampules should receive an exemption due to concerns surrounding extractables and leachables from labeling components.

- Products that are individually packaged in a tray or pouch and are considered sterile within the tray or pouch can be bar coded at the tray lidding or pouch level due to the fact that the product is not to be removed from that individual package until the time of administration.

- To accommodate unit of use bar codes on small packages, manufacturers should be allowed to remove text from the label if the text is repeated elsewhere on the outer package. An example of text that could be removed would be the manufacturer's name as this information is contained on the outer package as well as being part of the NDC information which will be encoded in the unit of use bar code.

- Due to space constraints on unit dose blisters, placing bar codes across perforations should be allowed as long as the placement does not affect the ability of the bar code to be scanned accurately with common hand-held scanners. By allowing these codes to be placed across perforations, it leaves more printing space on the unity cavity for other required information.

- Bar coding lot number and expiration date information should not be a requirement of the final rule.

- Prescription drug samples should not require a bar code.

- Bar code can be any linear bar code symbology including UPC, UCC/EAN-128 and RSS to allow manufacturers flexibility in selecting the bar code symbology that best fits their needs.

Sweeney, Fay

From: Werner, Kim
Sent: Wednesday, June 04, 2003 9:16 AM
To: Powell, Kathy; +US Reg - ED Team
Subject: RE: Call for comments response

Hi Kathy,

Your submission has been scheduled for 6/11. Yolanda will be your publisher.

Continue to send all correspondence to the +US Reg Ed team.

Please ensure that the Production Group or Publisher receives your Cover Letter and Form one day prior to the scheduled submission date.

Thank you

Regards,

Kim Werner
Sr. Publishing Specialist
US Regulatory Affairs,
FOC SE2-845
(302) 886-5456

-----Original Message-----
From: Powell, Kathy
Sent: Wednesday, June 04, 2003 9:10 AM
To: +US Reg - ED Team
Subject: Call for comments response

Good Morning,

I need to schedule a submission to the FDA to respond to the proposed bar code rule call for comments.
The deadline to submit comments in June 12th. Thanks.

Kathy Powell
Labeling Associate
kathy.powell@astrazeneca.com
(302) 886-2135