

March 1, 2005

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

Re: Comment on Docket No. 2004N-0535  
Medwatch: Food and Drug Administration Medical Products Reporting Program

To Whom It May Concern:

We do not have any adverse comments regarding this docket. However, since the MedWatch 3500A form is being revised, we are asking that the following improvements be made at the same time. These suggestions do not affect the appearance of the proposed form – only the functionality.

We appreciate the FDA's efforts to provide a MedWatch form in a fillable format. This is a tremendous aid to manufacturers and importers.

- 1) We would like to see the date fields formatted to the required MM/DD/YYYY format. The current MedWatch allows this date format to be entered, but immediately reverts many of the fields to a MM/DD/YY format when the user tabs to the next field. FDA requires a 4-digit year format. This problem specifically affects sections C7, D4, D7, D10, F6, F8, F11, F13, G4, and H4.
- 2) Also for the date fields, we are asking that each field allow the entry of NA, UNK, or NI. (Exception: B4 and G4 should be completed with a date.) This change avoids the need to specify NA, NI, and UNK in section H10 when the dates are unknown.
- 3) If the 3500A instructions are going to be revised as well, please clearly specify if the manufacturer is required to submit Event Problem Codes (Patient Code, Device Code) in section H10 – specifically when NO MedWatch report is received from a health care professional, user facility or other entity.

When no MedWatch report is received, the manufacturer is not required to complete Section F – however, better clarification is needed in the form instructions that these codes are required in Section H10, with the designation of “labeled” or “unlabeled”.

Thank you for considering our comments. I apologize that we are a few days late outside the comment period.

Sincerely,



Christine Posin  
OCRA MDR Network  
Orange County Regulatory Affairs Discussion Group

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