DuPont Pharmaceuticals Company

July 2, 2001

**VIA COURIER**

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

**SUBJECT: PROVIDING REGULATORY SUBMISSIONS IN ELECTRONIC FORMAT - POSTMARKETING EXPEDITED SAFETY REPORTS**
**Docket No. 01D-0185 (Request for Comments)**

Dear Sir or Madam:

Reference is made to the above referenced draft guidance and request for comments that was published in the May 4, 2001 edition of the FEDERAL REGISTER.

Enclosed for consideration are comments from the DuPont Pharmaceuticals Company concerning this draft guidance.

We appreciate the opportunity to provide comment on the draft guidance.

Sincerely,

Jamie Warner

Jamie Warner
Director, Regulatory Affairs
Labeling and Emerging Markets

Enclosure

Submitted in Duplicate

01D-0185

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**GUIDANCE FOR INDUSTRY**
**PROVIDING REGULATORY SUBMISSIONS IN ELECTRONIC FORMAT**
**POSTMARKETING EXPEDITED SAFETY REPORTS**
**COMMENTS**
**DOCKET NO. 01D-0185**

**DuPont Pharmaceuticals Company**

Members of the Worldwide Pharmacovigilance (WPV) Steering Committee and the Information Resources Group of the DuPont Pharmaceuticals Company have reviewed the Draft Guidance entitled "Providing Regulatory Submissions in Electronic Format - Postmarketing Expedited Safety Reports" (FEDERAL REGISTER: May 4, 2001, Volume 66, Number 87, Docket No. 01D-0185) and submit the following comments/suggestions for consideration:

## II. GENERAL ISSUES

### B. Electronic Transport Format

Lines 80-82 - The text of the draft guidance states:

"In November 2000, the ICH M2 working group revised the specifications for electronic submission of individual case safety reports consistent with E2BM.[3] The revised electronic specifications will be implemented by the FDA concurrently with implementation of E2BM."

DuPont Pharmaceuticals Comment: Further clarification needs to be made as to whether or not the FDA will accept the original M2 format (M2 spec v. 2.24, DTD v. 2.0).

### E. Sending in the Submission

Lines 105-108 - The text of the draft guidance states:

"...We prefer that you send the ICSR using the EDI gateway because this allows the most efficient processing of the reports. ICSR attachments, however, should be sent ***only*** on physical media."

DuPont Pharmaceuticals Comment: Please clarify if and when there will be a future opportunity to submit ICSR attachments via electronic media.

## F. Notification of Receipt of Report by the FDA

Lines 122-124 - The text of the draft guidance states:

"Once a submission reaches the EDI gateway and is successfully recognized and decrypted, an EDI gateway acknowledgement will be returned to the sender. The date of this acknowledgement will serve as the official receipt date of the submission."

DuPont Pharmaceuticals Comment: Please indicate the anticipated turnaround time for the acknowledgement.

Lines 126-129 - The text of the draft guidance states:

"For submissions sent via the EDI gateway, an automated standard generalized markup language (SGML) acknowledgment message, which gives the status of each report in the transmission, will be returned to you via the gateway."

DuPont Pharmaceuticals Comment: Please clarify the impact on the receipt date of an electronic submission if the EDI gateway acknowledgement is received but there is a subsequent problem with the E2B data content or format. Also, further clarification is needed on what the impact of the receipt date would be of an electronic submission if the FDA or gateway gets "backlogged", the length of time to wait and who to notify if acknowledgement is not received, and if the report should be sent again.

Lines 131-133 - The text of the draft guidance states:

"For submissions sent on physical media, the Agency will determine the receipt date as it does with submissions sent to the FDA on paper (i.e., receipt date is the date it arrives at the Agency)."

DuPont Pharmaceuticals Comment: Please clarify the impact on the receipt date of a submission sent on physical media if the FDA determines there are problems with the submission as well as the timeframe that the Agency will use relative to alerting a manufacturer to problems.

Line 136 - The text of the draft guidance states:

"This resubmission should take place as soon as possible."

DuPont Pharmaceuticals Comment: Please identify the timeframe given for resubmissions and if the report will be deemed late if resubmission is needed. Further clarification needs to be made regarding whether the resubmission applies to submissions sent via the EDI Gateway.

## III. ORGANIZING THE ELECTRONIC SUBMISSION

### A. ICSR

Line 195-196 - The text of the draft guidance states:

"The identification numbers used for followup reports should remain unchanged from those included in the original report. Once a field is populated, you should not change the information contained in it for any subsequent report."

DuPont Pharmaceuticals Comment: We believe that the phrase should read "Once an identifier field is populated" since data fields can legitimately change in subsequent reports.

### B. ICSR Attachments

Line 265

"Table 4: Document Information Fields in ICSR Attachments"

DuPont Pharmaceuticals Comment: The Subject field contains two pieces of data (A.1.10.1 and A.1.10.2). Further clarification needs to be made with respect to what type of delimiter should be used.

Lines 271-272 - The text of the draft guidance states:

"To help us match the attachment to the ICSR, you should use the manufacturer's control number for the ICSR as the file name for the ICSR attachment with *pdf* as the extension."

DuPont Pharmaceuticals Comment: Please clarify if there is or should there be a method to alert the FDA to the existence of an attachment for a particular ICSR.


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