DuPont Pharmaceuticals Company

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May 10, 2001

VIA COURIER

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

SUBJECT: POSTMARKETING SAFETY REPORTING FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS INCLUDING VACCINES
Docket No. 01D-0056 (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Reference is made to the above-referenced draft guidance and request for comments that was published in the March 12, 2001 edition of the FEDERAL REGISTER.

Enclosed for consideration are comments from the DuPont Pharmaceuticals Company concerning this draft guidance.

We appreciate the opportunity to provide comment on the draft guidance.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-0056

C12

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GUIDANCE FOR INDUSTRY
POSTMARKETING SAFETY REPORTING FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS INCLUDING VACCINES
COMMENTS
DOCKET NO. 01D-0056

DuPont Pharmaceuticals Company

Members of the Worldwide Pharmacovigilance Steering Committee of the DuPont Pharmaceuticals Company have reviewed the Draft Guidance entitled "Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines" (FEDERAL REGISTER: March 12, 2001, Volume 66, Number 48, Docket No. 01D-0056) and submit the following comments/suggestions for consideration:

Lines 189-191 - The text of the draft guidance states:

"An adverse experience is any undesirable event that is associated with the use of a drug or biological product in humans whether or not considered product-related by the applicant."

DuPont Pharmaceuticals Response: We believe that the new definition of an adverse experience (AE) is inconsistent with that provided in the Glossary of the document where the phrase "by the applicant" is not included. Currently, an AE is reported even though the reporter may secondarily state that the event is not related to drug use. The new guidance will limit the reporting of events deemed unlikely related to the drug by the reporter.

Lines 216-219 - The text of the draft guidance states:

"Adverse experiences from studies must only be submitted to the FDA if the applicant believes that there is a reasonable possibility that the drug or biological product caused the adverse experience (see §§310.305(c)(1)(ii), 314.80(e)(1), and 600.80(e)(1))."

DuPont Pharmaceuticals Response: We believe that compliance with ICH guidelines may be compromised when causality assessment is determined solely by the applicant. Both the applicant's and the reporter's causality determination should be considered when evaluating reportability. Otherwise, guidance should be provided to support consistent causality determination.

Lines 762-764 - The text of the draft guidance states:

"Reports of serious, unexpected adverse experiences described in the scientific literature should be submitted for products that have the same active moiety as a product marketed in the United States."

DuPont Pharmaceuticals Response: We believe that compiling adverse event data from the literature and submitting reports for another applicant's product would not help identify safety concerns about our product. The applicant who holds an NDA has specifically defined its product chemically, physically, and pharmacologically through its own development process. The assessment of safety requires the same rigor as that for efficacy. Assessing reported adverse events for moieties, which are not defined through the applicant's NDA process, may hinder the applicant's efforts to continue meaningful safety surveillance. We request the FDA reconsider this recommendation.

Lines 807-808 - The text of the draft guidance states:

"Reports of foreign serious, unexpected adverse experiences should be submitted for products that have the same active moiety as a product marketed in the United States."

DuPont Pharmaceuticals Response: We reiterate our belief that submitting reports for another applicant's product would not help identify safety concerns about our product. The applicant who holds an NDA has specifically defined its product chemically, physically, and pharmacologically through its own development process. The assessment of safety requires the same rigor as that for efficacy. Assessing reported adverse events for moieties, which are not defined through the applicant's NDA process, may hinder the applicant's efforts to continue meaningful safety surveillance. We request the FDA reconsider this recommendation.

Line 1465 – The text of the draft guidance states:

"Disability – A substantial disruption in one's ability to conduct normal life functions."

DuPont Pharmaceuticals Response: The definition of "disability" should be more specific. Interpretations vary concerning what constitutes "normal life function." Guidance should be provided to support consistent disability assessment.

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