



Central Research

May 3, 2000

Regulatory CMC Operations

5 2 9 3 '00 MAY -4 A 9 :30

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Docket No. 00D-0087; *Draft Guidance for Industry on IND Meetings for Human Drugs and Biologics; Chemistry, Manufacturing, and Control Information*

Dear Dockets Management Branch

We appreciate the opportunity to provide comments on *Draft Guidance for Industry on IND Meetings for Human Drugs and Biologics; Chemistry, Manufacturing, and Control Information* as requested in the announcement published in the Federal Register of February 4, 2000 (65FR5645). We endorse the comments provided on this guideline by the Pharmaceutical Research and Manufacturers of America under separate cover. In addition, we would like to comment on several areas of the guidance of particular concern to Pfizer.

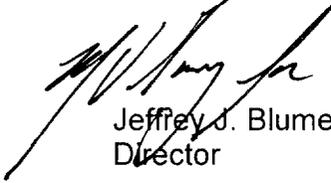
The emphasis in the guidance on joint, multidisciplinary meetings will likely lead to reduced time and focus on topics in the Chemistry, Manufacturing and Controls (CMC) arena that are critical to the success of the filing and approval process. Pfizer has found that these meetings with the Agency at key milestones have become critical to the success of the regulatory process. We encourage the FDA to provide guidance that may lead to increased access where appropriate, rather than providing a position that may decrease an Applicant's interactions with the Agency. We acknowledge the time of the reviewers is extremely valuable and we do not want to provide additional time burdens. However, we feel that effective meetings and increased specific applicant-reviewer interactions actually save time in the long-term by streamlining reviews and reducing the numbers and cycles of queries to the Applicant. Therefore, we encourage the guidance to advocate focused CMC specific meetings rather than discouraging them in preference to broad, multidisciplinary meetings. We also encourage that the Agency take these issues into consideration regarding the companion guidance entitled *Formal Meetings with Sponsors and Applicants for PDUFA Product* (Dated February 2000) so that the position encouraging focused CMC specific meetings is consistent.

00D-0087

C-8

We also would recommend that the guidance acknowledge that in addition to the many technical CMC issues that may be relevant for dialogue with the Agency, that some aspects of review logistics are appropriate topics for discussion. Often in the increasingly complex development programs that the industry and the Agency are dealing with, these issues are becoming critical for the programs. Examples of these logistics may include inter-division and inter-center interactions within the FDA. While inter-division consultations are not unusual, and the inter-center agreements have facilitated designation of review responsibilities, the details of logistics of how the submission and review will occur may be an impediment to timely submission and review unless there are clear understandings between the Agency and the applicant.

Sincerely,

A handwritten signature in black ink, appearing to read 'Jeffrey J. Blumenstein', written over a white background.

Jeffrey J. Blumenstein, Ph.D
Director

FedEx USA Airbill

814881827701

0200

FedEx Retrieval Copy

1 From
 Date May 3, 2000 Sender's FedEx Account Number 0063 00189
 Sender's Name Jeffrey Blumenstein Phone 860 441-0429
 Company Pfizer Inc
 Address Eastern Point Road ms 7040
 City Groton State CT ZIP 06340

2 Your Internal Billing Reference

3 To
 Recipient's Name Dockets Mgmt Branch (HFA-305)
 Company Food and Drug Administration
 Address 5630 Fishers Lane Rm 1061
 We cannot deliver to PO boxes or PO ZIP codes

to 'HOLD' at FedEx location, print FedEx address here

City Rockville State MD ZIP 20852



4a Express Package Service *Packages up to 150 lbs.*
 1 FedEx Priority Overnight *Next business morning* 5 FedEx Standard Overnight *Next business afternoon* 6 FedEx First Overnight *Earliest next business morning delivery to select locations*

3 FedEx 2Day* *Second business day* 20 FedEx Express Saver* *Third business day*

4b Express Freight Service *Packages over 150 lbs.*
 7 FedEx 1Day Freight* *Next business day* 8 FedEx 2Day Freight *Second business day* 83 FedEx 3Day Freight *Third business day*

5 Packaging ** Declared value limit \$500*
 6 FedEx Letter* 2 FedEx Pak* 1 Other Pkg. *Includes FedEx Box, FedEx Tube, and other carrier pkg.*

6 Special Handling
 3 Saturday Delivery *Available for FedEx Priority Overnight and FedEx 2Day to select ZIP codes* 3 Sunday Delivery *Available for FedEx Priority Overnight to select ZIP codes* 1 HOLD Weekday at FedEx Location *Not available with FedEx First Overnight* 3 HOLD Saturday at FedEx Location *Available for FedEx Priority Overnight and FedEx 2Day to select locations*

Does this shipment contain dangerous goods?
 One box must be checked.
 No 4 Yes *As per attached Shipper's Declaration* Yes Shipper's Declaration not required
 6 Dry Ice *Dry Ice, 8, UN 1845* kg
 Cargo Aircraft Only

7 Payment Bill to: Enter FedEx Acct. No. or Credit Card No. below. Obtain Recip Acct. No.
 1 Sender *Must be in person to bill* 2 Recipient 3 Third Party 4 Credit Card 5 Cash/Check

FedEx Acct. No. _____ Exp. Date _____
 Credit Card No. _____
 Total Packages 1 Total Weight 44 lb. Total Charges _____
 Credit Card Auth. _____

8 Release Signature Sign to authorize delivery without obtaining signature.

We warrant we will endeavor to deliver this shipment without obtaining a signature if you so authorize us and hold us harmless from any resulting claims.

360

Rev. Date 11/99 • Part #154915 • GBFE 7/99