
Manual of Standard Operating Procedures and Policies

Communication

Distribution of "Dear Doctor" Letters

SOPP 8108

Version #2

June 7, 2002

1. Purpose

The purpose of this document is to describe the process for distributing important information about drugs, including biological drug products, under 21 CFR 200.5 (commonly referred to as "Dear Doctor Letters").

2. Definition

Dear Doctor Letter

A letter drafted by a licensed biological product manufacturer, CBER, or the Agency addressed to doctors, pharmacists, and health professionals regarding important new product issues, e.g., new warnings, other safety information, or other important changes to the prescribing information (labeling).

3. Background

The regulations in 21 CFR 200.5 describe the mailing of important information about drugs (which includes biologics). The regulations were crafted with the expectation, in the interest of public health and safety, that there would be occasion for manufacturers, distributors, and FDA to provide new or updated information about drugs and biological products to healthcare practitioners. The three categories for special mailings under this section include: "IMPORTANT DRUG WARNING"; "IMPORTANT PRESCRIBING INFORMATION"; and "IMPORTANT CORRECTION OF DRUG INFORMATION".

4. Policy

CBER will make Dear Doctor letters available to the appropriate persons and organizations in a timely manner.

5. Responsibilities and Procedures

A. OCBQ

The Associate Director for Labeling Policy and Medical Communication (ADLPMC), Office of Compliance and Biologics Quality (OCBQ) or other designated individual, has lead responsibility within OCBQ for:

- Upon completion of the Dear Doctor letter, obtaining a copy of the final letter in PDF and Word format.
- Submitting the final letter to OCTMA and FDA's Medwatch. MedWatch will post the entire letter and disseminate it to all individuals on their distribution list, as well as those organizations with established partnerships with MedWatch.

- Notifying the following individuals that the letter has been posted:
 - Director of the CBER Division responsible for the product involved
 - Director, OCBQ
 - Deputy Director for Medicine, CBER
 - Director, OBE
 - District Office where firm is located.
 - Program Inspection Branch, Division of Inspections and Surveillance, OCBQ for inclusion in pre-inspection briefing materials for investigators.

B. OCTMA

OCTMA will:

- Provide a copy of each letter to:
 - FDA, Office of Policy, Planning and Legislation
 - FDA, Office of Public Affairs
- Post Dear Doctor letters developed by the Center on CBER's website. When Dear Doctor letters are developed by biological product manufacturers, OCTMA will provide a hyperlink to the letter posted by MedWatch.
- Disseminate letters or information about how to obtain a copy of the letter via the automated List-server, FAX Information System, or paper copy if requested.

6. Effective Date

June 7, 2002

7. History

Written/Revised	Approved	Approval Date	Version Number	Comment
RMCC	Robert Yetter, Ph.D.	June 7, 2002	2	Add OBE to the letter notification list
OCTMA, OCBQ, OD, OTRR, OBRR, RMCC	Robert Yetter, Ph.D.	December 6, 2001	1	Original document

Updated: June 11, 2002