OFFICE OF THE CENTER DIRECTOR

Drug Safety Newsletter

CONTENTS

PURPOSE

- This MAPP provides a general description of the policy and procedures by which the Center for Drug Evaluation and Research (CDER) produces and distributes the quarterly *Drug Safety Newsletter* (the Newsletter).

- This MAPP covers:

  - Selection of *Drug Safety Newsletter* content
  - Establishment of policy and procedures for the Newsletter, including development and clearance
  - Resolution of editorial, format, and content questions and issues as they arise
  - Distribution and archiving of the Newsletter

- This MAPP does not cover FDA or CDER communications other than the *Drug Safety Newsletter*.

BACKGROUND

- The *Drug Safety Newsletter* is one venue for communicating safety information to healthcare professionals and consumers. Sources of information for the *Drug Safety Newsletter* can include (but are not limited to) postmarketing safety reviews conducted by the Office of Surveillance and Epidemiology (OSE), safety-related reviews conducted by other CDER offices, such as the Office of

New Drugs (OND), Office of Compliance, or Office of Generic Drugs, as well as selected safety-related articles written specifically for the *Drug Safety Newsletter.*

- Topics are selected based on factors such as (1) the likely importance of a topic for patient care and public health, (2) the seriousness of an adverse event, and (3) the timeliness of a topic given other publications or events of public interest. In addition, topics of special interest, such as clinical or methodological approaches pertinent to drug safety questions may be included.

- The *Drug Safety Newsletter* links to other related FDA safety communications for the convenience of readers and is not intended to duplicate them.

REFERENCES

- FDA Adverse Event Reporting Regulations, 21 CFR 310.305, 314.80, 314.98, and 600.80
- FDA guidance for industry on *Drug Safety Information - FDA's Communication to the Public*
- FDA guidance for industry on *Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment*

DEFINITION

- **Safety Review:** For the purpose of this MAPP, a safety review is a CDER review that includes an assessment of one or more potential safety risks.

POLICY

- The *Drug Safety Newsletter* will highlight and communicate important safety information reviewed and analyzed by FDA that might not otherwise be easily accessible by healthcare professionals and the public.

- The *Drug Safety Newsletter* will have a target audience of healthcare professionals.

- The Drug Safety Newsletter will increase the transparency and openness of the FDA to healthcare professionals and the public in the area of postmarketing drug safety analyses.

- CDER's Associate Director for Safety Policy and Communication will make the final decision on topics to be included in each issue of the *Drug Safety Newsletter*, with input from the Newsletter Editorial Board.

ORGANIZATION

- **Editorial Board**

  The Editorial Board includes at least one member from each of the following CDER offices: Office of Surveillance and Epidemiology, Office of New Drugs, Office of Generic Drugs, Office of Compliance, Office of Regulatory Policy, and Office of Training and Communication. In addition, it will include one representative from the Center for Biologics Evaluation and Research, and one from the Center for Devices and Radiological Health, to assist in consultation and coordination as needed. CDER's Associate Director for Safety Policy and Communication chairs the Editorial Board.

- **Newsletter Production Team**

  The Newsletter Production Team includes members from CDER's Safety Policy and Communications Staff and Office of Training and Communication. The Senior Scientific Editor is the lead member of the Newsletter Production team.

RESPONSIBILITIES

The Associate Director for Safety Policy and Communication will:

- Chair the Editorial Board
- Provide overall program direction to the Newsletter staff/production team
- Clear each issue of the Newsletter for posting, obtaining review and clearance from the directors of OND and OSE or their respective designees (concurrently), and then sequentially from CDER's Associate Director for Policy to CDER's Director, or their respective designees

The Editorial Board will:

- Meet quarterly, in advance of the production of each issue, and more often as needed
- Review possible topics and recommend priorities for publication
- Advise the Chair of the Editorial Board and the Senior Scientific Editor regarding questions of editorial policy as needed

The Senior Scientific Editor will:

- Lead the Newsletter Production Team
- Advise the Associate Director for Safety Policy and Communication on questions of editorial policy
- Respond to questions about Newsletter content and production

The Newsletter Production Team will:

- Assemble possible topics for Editorial Board review
- Write Newsletter content

- Produce Newsletter as a Web product
- Facilitate Newsletter distribution through the Web
- Ensure that earlier issues of the completed Newsletter are maintained and accessible for future reference

PROCEDURES

Selection of Content

- The Senior Scientific Editor (or designee) will request a list of recommended topics from OND and OSE on a quarterly basis.

- OND and OSE will return a list of recommended topics to the Senior Scientific Editor (or designee) within the time frame specified.

- OND and OSE may forward additional Newsletter topics as they arise between quarterly requests.

- The Senior Scientific Editor maintains a list of recently completed reviews from the Office of Surveillance and Epidemiology (OSE) and monitors the Office of New Drug (OND) weekly report for updates and actions taken on safety issues under consideration for inclusion in the Newsletter.

- The Senior Scientific Editor, with assistance from other Production Team members as needed, assembles a package of possible topics for Editorial Board consideration, including
    - The list of recently completed reviews
    - Reviews related to publishing information on emerging safety issues
    - Recommendations or special considerations, if any

- The Editorial Board meets quarterly and at other times as needed, and identifies priorities for publication at least 2 months before the intended posting date.

- The final decision on topics for each issue of the Newsletter is made by the Associate Director for Safety Policy and Communication.

- Topics selected for the next issue of the Newsletter are communicated to the primary authors of related safety reviews.

- If the content of a safety review of interest to the Editorial Board is expected to appear in a non-FDA publication, and the manuscript has been accepted for publication, then the Editorial Board will generally not publish an article based on the safety review of interest if the focus of the article would be duplicative. In cases where future publication is possible but not imminent, then the Editorial Board will continue considering the topic as above.

Development of Content

- The Newsletter Production Team writes the first draft of articles for the Newsletter consisting of summaries of the recommended reviews.

- The Newsletter Production Team sends the first draft to appropriate CDER staff as relevant to the content of the article, such as the primary author(s) of the review, or subject matter experts in other program areas as needed for a particular article, to ensure that the summary is accurate.

- Articles are sent through the channels established by each organizational component to facilitate effective management of document flow and work process.

- The primary author or authors of the safety review (and supervisor, if relevant) provide comments to the Newsletter Production Team within 5 business days. A second draft may be needed if substantive changes are requested by CDER staff during review of the first draft.

- Accuracy of article content should be addressed during the development of each article.

- The primary author or authors of the safety review should indicate whether the published Newsletter should acknowledge the author by name.

- Other subject matter experts in CDER may contribute occasional feature articles, in consultation with the Editorial Board or the Senior Scientific Editor.

- The Division of Information Disclosure Policy staff members review each article and recommend redaction of any non-disclosable information. Portions of the article may need to be rewritten to eliminate non-disclosable information.

- Articles are drafted and put into clearance at least 1 month before the quarterly posting date of the Newsletter – see the attached timeline, "*Drug Safety Newsletter* Production Schedule Timeline."

Review and Clearance

- After development, each article will be cleared by the following staff:
  - CDER's Associate Director for Safety Policy and Communication
  - Director of OND or designee
  - Director of OSE or designee
  - Director of respective organizational component, for those articles contributed by other subject matter experts in CDER as mentioned above
  - CDER's Associate Director for Policy or designee
  - CDER's Director or designee

- Clearance is requested with a turn-around time of 5 business days at each level. The documents are returned to the Senior Scientific Editor after each clearance to be modified as needed before being passed to the next level. The order of clearance is:

- CDER's Associate Director for Safety Policy and Communication
- Directors of the OND and OSE or their respective designees (concurrently)
- CDER's Associate Director for Policy or designee
- CDER's Director or designee

Production

- The Newsletter Production Team assembles, arranges, and posts the Newsletter as a Web page.

- The Production team works with the Associate Director for Safety Policy and Communication, and coordinates with other offices as needed, to ensure posting at an agreed upon date, generally 5 business days after receiving the completed and assembled Newsletter.

Distribution

- The link and announcement of the new issue of the Newsletter is announced on the FDA Web site, is distributed through the MedWatch Partners Program to its listserv subscribers, and may be distributed through other Agency electronic lists if available.

- Courtesy notices of Newsletter publication are provided to sponsors whose products are the subject of articles and to international regulatory agencies as follows:
  - The notices are sent by fax at least 24 hours before posting the Newsletter
  - Notices to sponsors are sent by the Safety Policy and Communication Staff to sponsor contacts provided by the appropriate OND Division
  - Notices to international regulatory agencies are sent by the Office of International Programs

Updates and Corrections

- The Editorial Board will consider on a case-by-case basis whether the Newsletter should provide updates on previous Newsletter items. The Board will consider whether newly emerging information would lead to conclusions substantially different than those suggested in previous Newsletter items and whether the new information is readily available elsewhere.

- The Senior Scientific Editor will determine whether corrections to previous Newsletter items are needed. For substantive corrections, the text of the correction should be reviewed with the CDER staff who contributed to the content of the article and cleared through the same channels described above under "Review and Clearance" for the original article. Once the correction is cleared, the Senior Scientific Editor will provide it to the production team to make the correction on the Web page.

- Should an error in Newsletter content be identified, a correction will be made on the Web page as soon as possible.

Contacts

- Questions about Newsletter content and production should be directed to the Senior Scientific Editor.
- Questions about specific drugs not relating to Newsletter content or production should be directed to CDER's Division of Drug Information.

Past Issues

- The Newsletter Production Team ensures that earlier issues of the completed Newsletter are maintained and accessible for future reference.

EFFECTIVE DATE

The MAPP is effective upon date of publication.

ATTACHMENT

DRUG SAFETY NEWSLETTER PRODUCTION SCHEDULE TIMELINE

Activity	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec	Jan
April Issue														
Topic Selection/Approvals														
First Drafts/Writing														
Internal Review														
Clearance														
Web preparation/Distribution														
July Issue														
Topic Selection/Approvals														
First Drafts/Writing														
Internal Review														
Clearance														
Web preparation/Distribution														
October Issue														
Topic Selection/Approvals														
First Drafts/Writing														
Internal Review														
Clearance														
Web preparation/Distribution														
January Issue														
Topic Selection/Approvals														
First Drafts/Writing														
Internal Review														
Clearance														
Web preparation/Distribution														