OFFICE OF COMPLIANCE

Standing Operating Procedures for Handling NDA/ANDA Field Alert Reports

CONTENTS

PURPOSE This Mapp establishes a system for evaluating new drug application (NDA) and abbreviated new drug application (ANDA) Field Alert Reports and provides instructions to the responsible CDER units for handling those reports.

BACKGROUND

- The NDA/ANDA Field Alert reporting requirements in 21 CFR 314.81(b)(1)(i) and (ii) became effective on May 23, 1985. This regulation requires holders of NDAs and ANDAs to submit certain information about distributed drug products to the jurisdictional FDA district office within 3 working days of receipt by the applicant. These reports, in contrast to the "postmarketing reporting of adverse drug experiences" under § 314.80, deal with a variety of drug product quality issues and are of interest to both field and CDER Headquarters FDA components.

- On February 27, 1987, several copies of Form FDA 3331 (which contains an information/instruction sheet) were sent to each application holder along with a cover letter from CDER's Office of Compliance (HFD-300).

- Compliance Program 7356.021, Drug Quality Reporting System DQRS, NDA-Field Alert Reporting, provides the background and the inspection and reporting requirements for these reports.

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REFERENCES

- The NDA/ANDA Field Alert reporting requirements of 21 CFR 314.81(b)(1)(i) and (ii).
- NDA-Field Alert Report, Form FDA 3331, Postmarket Surveillance Team (HFD-336).
- Compliance Program 7356.021, Drug Quality Reporting System DQRS, NDA-Field Alert Reporting.

RESPONSIBILITIES

- **District Offices**

  1. In the districts, the Postmarket Surveillance Team (PST) Coordinator or other designated officer is responsible for ensuring that the Field Alert Report is evaluated promptly, and that a proper follow-up is conducted, if necessary.

  2. The District Recall and Emergency Coordinator, or other designated officer, is responsible for determining that the NDA-Field Alert Report sections of Attachment B, Chapter 5, of the Regulatory Procedures Manual are completed and submitted with regard to a firm's compliance with 21 CFR 314.81(b)(1)(i), and (ii).

- **Office of Compliance**

  1. Upon receipt of the report, the Postmarket Surveillance Team (HFD-336) will evaluate the initial report and the district's follow-up information.

  2. If HFD-336 determines during its evaluation that the report or the district's investigational findings concern a potentially significant problem, copies of the report and findings will be sent within 3 working days to the Office of Compliance Drug Recall Staff (HFD-300) and the Division of Manufacturing and Product Quality (HFD-320) for their evaluation.

  3. If HFD-336 concludes that a firm is not in compliance with 21 CFR 314.81(b)(1)(i)or(ii), HFD-300 and HFD-320 will be informed. HFD-320 is responsible for determining whether the alert involves significant CGMP problems. HFD-336 is responsible for determining whether the firm failed to

comply with the NDA/ANDA Field Alert Report requirements and recommending the appropriate regulatory action to the district with a copy to HFD-320/HFD-300 and to the Office of Review Management (ORM) or the Office of Generic Drugs (OGD), as appropriate.

4. An individual will be designated by HFD-320 to be responsible for receiving and tracking all NDA-Field Alert Reports and related issues in their respective divisions.

- **Office of Review Mange and Office of Generic Drugs**

1. HFD-336 will forward a copy of the initial report and any follow-up assignments to the supervisory chemist in the affected CDER review division for his/her information and/or review. For generic drugs, the reports will be forwarded to the Director, Division of Chemistry I or II.

PROCEDURES

- **District Offices**

1. The districts are responsible for receiving the reports from the applicants, evaluating them, and making a decision as to what course of action, if any, must be taken. If the problem appears to be significant, the appropriate follow-up action should be taken immediately.

2. As required by Compliance Program 7356.006, a copy of the report should be forwarded by the district office to the Office of Compliance, Postmarket Surveillance Team (HFD-336), within 5 working days. The action plan and any available investigational information also should be forwarded to HFD-336 within the 5 working day period.

- **Office of Compliance**

1. A copy of all reports, including the district office's evaluations, will be forwarded by HFD-336 to the affected CDER review division for their comments within 3 working days of receipt. A copy will also be forwarded to the DQRS contractor for entry into the Drug Quality Reporting System (DQRS) database.

2. If HFD-300 and/or HFD-320 determines that the matter should be investigated or additional coverage is required, it should advise HFD-336 as soon as possible to issue an assignment. HFD-336 will act as the contact between the field and the Center. If HFD-336 determines during its evaluation that follow-up is warranted, it will issue an assignment to the affected district as soon as possible. HFD-336 will coordinate the preparation and issuance of the assignment with HFD-300, HFD-320, and the affected CDER review division. Copies of all assignments will be forwarded to HFD-300, HFD-320, and the affected CDER review division or OGD.

- **Office of Review Management and Office of Generic Drugs**

1. If the review division determines that additional information is needed, or concludes that an investigation is warranted, HFD-336 should be contacted within 3 working days after receipt to coordinate any follow-up. Prior to issuing follow-up assignments to the district office, HFD-336 will request the review division's comments. A routine response from the review division to HFD-336 is not necessary for reports where no follow-up is deemed necessary. A copy of the initial report, as well as any subsequent paperwork, should be entered into the NDA or ANDA drug file by the reviewing chemist of the review division involved.

EFFECTIVE DATE

This MAPP is effective upon date of publication.