NEW DRUG CHEMISTRY

Procedures for Evaluating and Handling Field Alert Reports

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PURPOSE

- This MAPP describes the procedures in the Office of New Drug Chemistry (ONDC) divisions and the Office of Review Management (ORM) review divisions for evaluating and handling new drug application (NDA) Field Alert Reports (FARs).

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 abbreviated new drug applications (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 21 CFR 314.80, deal with a variety of drug product quality issues and are of interest to both the field and the Center for Drug Evaluation and Research (CDER) headquarters.

- CDER MAPP 4723.1 was published on October 30, 1998, establishing certain procedures for evaluating and handling ANDA and NDA FARs. However, MAPP 4723.1 did not detail the procedures within the ORM and ONDC for evaluating and handling NDA FARs.

REFERENCES

- The NDA/ANDA Field Alert reporting requirements of 21 CFR 314.81(b)(1)(i) and (ii)
- CDER MAPP 4723.1, Standing Operating Procedures for Handling NDA/ANDA

RESPONSIBILITIES AND PROCEDURES

- **Division Document Room Staff**

  Places the incoming document into the archival jacket, codes it as correspondence and assigns it to a chemist in COMIS.

- **ORM Project Management Staff**

  1. Follows the usual procedures for submissions assigned to chemists.

  2. Ensures that comments from all disciplines are conveyed to the Office of Compliance Postmarket Surveillance Team (PMST), if appropriate, within 3 working days of receipt of all pertinent reviews.

  3. Ensures that the drug shortage MAPP 4730.1 is followed if the FAR reports a possible shortage.

  4. Ensures that appropriate information is conveyed to the firm (e.g. supplement requests).

- **ONDC Chemistry Staff**

  1. Reviews the FAR to determine whether action is requested on the FAR cover sheet. The FARs are frequently identified as "FYI" by the PMST, in which case a response is not necessary.

  2. Contacts the PMST coordinator indicated in the FAR cover memorandum if clarification of the request for comment is necessary.

  3. Consults as necessary with other disciplines. If a formal consult is necessary, it goes through the project manager.

  4. Responds to the PMST's request for comment on chemistry issues within 6 working days of receipt. This response can be by e-mail or fax with team leader concurrence and a copy to the project manager. All responses must be documented in the NDA file.

  5. Ensures that the firm's corrective action does not conflict with the requirements of the NDA.

6. Ensures that the NDA is updated as necessary (e.g., supplements, annual report).

EFFECTIVE DATE

This MAPP is effective upon date of publication.