PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

1. The authority citation for part 240 is amended by adding the following citation in numerical order to read as follows:

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77z–2, 77z–3, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78d, 78e, 78f, 78g, 78i, 78j, 78j–1, 78k, 78k–1, 78*l,* 78m, 78n, 78o, 78o–4, 78p, 78q, 78s, 78u–5, 78w, 78x, 78*ll,* 78mm, 80a–20, 80a–23, 80a–29, 80a–37, 80b–3, 80b–4, 80b–11, and 7201 *et seq.;* 18 U.S.C. 1350; and 12 U.S.C. 5221(e)(3), unless otherwise noted.

* * * * *

Section 240.3Cg–1 is also issued under Public Law 111–203, § 763, 124 Stat. 1841 (2010).

* * * * *

2. Add § 240.3Cg–1 to read as follows:

§ 240.3Cg–1 Notice to the Commission [and Financial Entity Exemption].

(a) A counterparty to a security-based swap that invokes the clearing exception under Section 3C(g)(1) of the Act (15 U.S.C. 78c–3(g)(1)) shall satisfy the requirements of Section 3C(g)(1)(C) of the Act (15 U.S.C. 78c–3(g)(1)(C)) by delivering or causing to be delivered the following additional information to a registered security-based swap data repository (or, if none is available, to the Commission) in the form and manner required for delivery of the information separately specified under § 242.901(d) of Regulation SBSR of this chapter:

(1) The identity of the counterparty relying on the clearing exception;

(2) Whether the counterparty invoking the clearing exception is a "financial entity" as defined in Section 3C(g)(3) of the Act (15 U.S.C. 78c–3(g)(3));

(3) Whether the counterparty invoking the clearing exception is a finance affiliate meeting the requirements described in Section 3C(g)(4) of the Act (15 U.S.C. 78c–3(g)(4));

(4) Whether the security-based swap is used by the counterparty invoking the clearing exception to hedge or mitigate commercial risk as defined in § 240.3a67–4 of this chapter;

(5) Whether the counterparty invoking the clearing exception generally expects to meet its financial obligations associated with the security-based swap by using any of the following:

(i) A written credit support agreement;

(ii) A written agreement to pledge or segregate assets;

(iii) A written third-party guarantee;

(iv) Solely the counterparty's available financial resources; or

(v) Means other than those described in paragraphs (a)(5)(i), (ii), (iii), and (iv) of this section;

(6) Whether the counterparty invoking the clearing exception is an issuer of securities registered under Section 12 (15 U.S.C. 78*l*) or subject to reporting requirements pursuant to Section 15(d) (15 U.S.C. 78o(d)) of the Act, and if so:

(i) The relevant Commission Central Index Key number for the counterparty invoking the clearing exception; and

(ii) Whether an appropriate committee of the board of directors (or equivalent body) of the counterparty invoking the clearing exception has reviewed and approved the decision to enter into a security-based swap subject to the clearing exception.

Additional Rule Text Under Consideration by the Commission

(b) For purposes of Section 3C(g)(1)(A) of the Act (15 U.S.C. 78c–3(g)(1)(A)), any person specified in paragraph (c) of this section that would be a financial entity within the meaning of the term in Section 3C(g)(3)(A) of the Act (15 U.S.C. 78c–3(g)(3)(A)) solely because of Section 3C(g)(3)(A)(viii) of the Act (15 U.S.C. 78c–3(g)(3)(A)(viii)) shall be exempt from the definition of financial entity.

(c) A person shall be eligible for the exemption in paragraph (b) of this section if such person:

(1) Is organized as a bank, as defined in Section 3(a)(6) of the Act (15 U.S.C. 78c), the deposits of which are insured by the Federal Deposit Insurance Corporation, a savings association, as defined in section 3(b) of the Federal Deposit Insurance Act (12 U.S.C. 1831), the deposits of which are insured by the Federal Deposit Insurance Corporation, a farm credit system institution chartered under the Farm Credit Act of 1971 (12 U.S.C. 2001), or an insured Federal credit union or State-chartered credit union under the Federal Credit Union Act (12 U.S.C. 1752); and

(2) Has total assets of $10,000,000,000 or less on the last day of the most recent fiscal year.

By the Commission.

Dated: December 15, 2010.

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2010–31973 Filed 12–20–10; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 58

[Docket No. FDA–2010–N–0548]

Good Laboratory Practice for Nonclinical Laboratory Studies

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is seeking comment on whether to amend the regulations governing good laboratory practices (GLPs). The Agency decided that to require a GLP quality system for all facilities/laboratories, as well as to more completely address nonclinical studies as they are presently conducted, the Agency would need to modify the existing regulations.

DATES: Submit either electronic or written comments by February 22, 2011.

ADDRESSES: You may submit comments, identified by the Docket No. FDA–2010–N–0548, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Fax:* 301–827–6870.
- *Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and docket number for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in the brackets in the heading of this document, into the "Search" box and follow the prompts

and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: C. T. Viswanathan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5346, Silver Spring, MD 20993–0002, 301–796–3394.

SUPPLEMENTARY INFORMATION:

I. Background

FDA's GLP regulations, part 58 (21 CFR part 58), were finalized on December 22, 1978 (43 FR 60013). As stated in its scope (§ 58.1), this regulation prescribes good laboratory practices for conducting nonclinical laboratory studies that support or are intended to support applications for research or marketing permits for products regulated by FDA, including food and color additives, animal food additives, human and animal drugs, medical devices for human use, biological products, and electronic products. A nonclinical laboratory study, as defined in § 58.3(d), is an * * * in vivo or in vitro experiment in which test articles are studied prospectively in test systems under laboratory conditions to determine their safety. The term does not include studies utilizing human subjects or clinical studies or field trials in animals. [It also] does not include basic exploratory studies carried out to determine whether a test article has any potential utility or to determine physical or chemical characteristics of a test article.

The conduct of nonclinical laboratory studies has changed markedly since issuance of this regulation in 1978. For example, it is presently common for nonclinical laboratory studies to be conducted across multiple testing facilities, or sites (multisite studies). When the regulation was originally finalized, however, most studies were conducted within a single facility. In addition, laboratories have expanded the use of electronic technology, both for laboratory instrumentation and as a means for collecting, storing, and reporting study data. Current part 58 does not specifically describe these modern arrangements and advances.

In 2006, FDA announced its Human Subject Protection/Bioresearch Monitoring (HSP/BIMO) initiative aimed at modernizing the Agency's regulations and policies governing the conduct of studies used to support submissions to FDA. In response to the announcement of the HSP/BIMO initiative, FDA received stakeholder recommendations that included suggestions for the revision of part 58. In 2007, FDA established an Agency-wide GLP working group (WG) to evaluate the existing regulation and determine if regulatory revision and/or guidance should be pursued. The WG gathered information as to the needs of each FDA center with regard to nonclinical laboratory studies, reviewed suggestions from external sources, conferred with the Environmental Protection Agency (EPA) which has a similar regulation, and performed a thorough evaluation of the existing regulations. The WG concluded that to ensure the integrity of the data in all nonclinical laboratory studies submitted to FDA, nonclinical laboratory facilities that conduct these studies need to follow a GLP quality system approach. Currently, the regulations governing nonclinical laboratory studies do not use such an approach consistently throughout part 58. A GLP quality system would allow nonclinical laboratories to develop standard operating procedures consistent with their specific operational needs as long as they satisfy regulatory requirements aimed at ensuring data integrity. The WG decided that to require a GLP quality system for all facilities/laboratories, as well as to more completely address nonclinical studies as they are presently conducted, the Agency would need to modify the existing regulations.

II. Agency Request for Information

FDA is soliciting public comments about whether to modify the existing regulations, and in particular about the areas FDA has identified as potentially appropriate for revision, as follows:

1. GLP Quality System

While many of the requirements of the existing regulation are consistent with a GLP quality system, FDA believes that modifications may be necessary to incorporate all basic elements needed for a comprehensive GLP quality system, such as that set forth in the internationally recognized standard, Quality management systems—Requirements ISO 9001, available from the International Organization for Standardization (ISO) at: *http://www.iso.org/iso/home.html*. Ultimately, any GLP quality system proposed for a facility must be capable of ensuring the integrity of resulting data. FDA is considering whether to include in the regulations a core set of essential elements for such a GLP quality system, including specifically mentioning management responsibility for all activities at the facility and specifying a requirement for standard operating procedures for all essential functions.

2. Multisite Studies

It is currently common practice for nonclinical laboratory studies to be performed across multiple sites (multisite studies), rather than for a single facility to conduct all aspects/phases of a study. FDA is considering revising the GLP regulations to specifically address the use of multisite studies through the addition of specific definitions to describe personnel and study aspects specific to multisite studies, *e.g.,* by requiring that an individual be designated as the responsible person for each site of a multisite study. Such an individual would be responsible for any phase(s) of the study conducted at the site and would report to the study director.

3. Electronic/Computerized Systems

Since the regulation was finalized, many laboratory systems have become fully automated. In addition, many facilities now employ computerized systems for managing general laboratory functions as well as for instrumentation in which such systems are integral components. While the present regulation does not preclude such electronic systems, several of the current regulatory requirements are more consistent with paper-based systems (*e.g.,* an individual as archivist § 58.190(c)); maintenance of copies of study protocols and the Master Schedule by the quality assurance unit (§ 58.35(b)(1) and (b)(2))). FDA is considering updating the regulation to reflect the use of electronic and computerized systems. FDA believes that any modifications to the regulation to reference electronic/computerized systems should be general, to accommodate changes and advances in technology.

4. Sponsor Responsibilities

Whether nonclinical laboratory studies are conducted by a sponsor or at a contracted facility, FDA believes that the study sponsor should clearly have responsibilities that the present regulation does not specifically mention, such as development and/or approval of study protocols. FDA is therefore considering amending the regulations to include additional specific responsibilities of sponsors of nonclinical laboratory studies.

5. Animal Welfare

In the United States, the Animal Welfare Act (7 U.S.C 2131–2159) governs the treatment and use of

animals, including their use for research purposes. FDA is soliciting comments regarding whether and how to receive documentation of compliance with these existing statutory provisions or comparable international standards governing the ethical and humane use of laboratory animals in nonclinical laboratory studies. This issue is not specifically addressed in the present regulation.

6. Information on Quality Assurance Inspectional Findings

When an FDA bioresearch monitoring (BIMO) inspection of a nonclinical study identifies problems, FDA often finds it difficult to determine whether the quality assurance unit (QAU) failed to adequately inspect the study, or whether the QAU made recommendations for corrective actions and management did not adequately respond. FDA is considering the addition of a requirement that the QAU prepare a yearly summary of general inspectional findings that would reveal problems that are not necessarily study-specific and that includes the recommendations made to management to resolve those problems. Such a report would be maintained at the facility and be made available to FDA upon request, usually during the course of a BIMO inspection.

7. Process-Based Systems Inspections

A number of procedures used in conducting a particular nonclinical laboratory study are common across many or even most studies conducted at the facility. Facilities often find it more resourceful to periodically inspect such procedures during systems inspections rather than repetitively as part of each study-specific inspection, as currently required in § 58.35(b). For example, it may be appropriate to periodically inspect procedures such as slide preparation for pathology studies as part of a facility's process-based systems inspections rather than for each study. FDA therefore is considering permitting a combination of systems inspections and study-specific inspections. The results of the appropriate systems inspection(s) would be referenced in the study-specific inspection reports relevant to those aspects of the procedures for the study under inspection.

8. Test and Control Article Information

When reviewing and inspecting nonclinical laboratory studies, particularly those submitted for new drugs (human and animal), basic information about the test article, such as strength, purity, stability, and for mixtures thereof, concentration and uniformity, is often absent from the laboratory's records, therefore precluding appropriate interpretation of the study results. Although the current regulations require that these parameters be determined (§ 58.105(a) and (b) and § 58.113(a)), the regulations do not specify who is to receive this information or include a timeframe for delivery of the information to the facility performing the nonclinical testing. FDA is therefore considering additional requirements under the sections in the regulations discussing test and control characterization (§ 58.105) and mixtures of articles with carriers (§ 58.113), including timeframes for provision of this information to the study director.

In addition, sponsors have requested the ability to cite compliance with the applicable good manufacturing requirements (*i.e,* parts 210 and 211, *etc.* as relevant) regarding the specifications, quality, and integrity of the test article. FDA is considering whether to accept compliance with either the specifics that would be required under a revised part 58, subpart F or the relevant good manufacturing requirements.

9. Sample Storage Container Retention

FDA's regulations currently require that facilities maintain test article storage containers for the duration of the study (21 CFR 58.105(c)). FDA believes that compliance with the regulatory requirements for the handling of test and control articles, which include documentation of receipt, distribution, and use of each batch (§ 58.107(d)) provides adequate information about the use and integrity of study samples. Therefore, FDA is considering eliminating the requirement at § 58.105(c).

FDA welcomes comments from all interested persons on these issues and any other concerns related to the current GLP regulations, including recommendations as to the best method(s) for addressing such concerns.

III. Comments

Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) either electronic or written comments regarding this document. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

This advance notice of proposed rulemaking is issued under section 201 *et al.* of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et al.*) and under authority of the Commissioner of Food and Drugs.

Dated: December 15, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–31888 Filed 12–20–10; 8:45 am]

BILLING CODE 4160–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 10–2279; MB Docket No. 10–65; RM–10595]

Radio Broadcasting Services; Jewett, TX

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; dismissal.

SUMMARY: At the petitioner's request, the Audio Division has dismissed the proposal of Charles Crawford to allot Channel 232A at Jewett, Texas. Crawford had filed a petition for rule making proposing the allotment of Channel 232A at Jewett, Texas, as the community's first local FM transmission service.

FOR FURTHER INFORMATION CONTACT: Deborah Dupont, Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order,* MB Docket No. 10–65, RM–10595, adopted December 1, 2010, and released December 3, 2010. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC 20554. The complete text of this decision also may be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20554, (800) 378–3160, or via the company's Web site, *http://www.bcpiweb.com.* This document is not subject to the Congressional Review Act. The Commission is, therefore, not required to send a copy of this *Report and Order* in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* U.S.C. 801(a)(1)(A), because the proposed rule was dismissed.

Federal Communications Commission.

John A. Karousos,

Assistant Chief, Audio Division, Media Bureau.

[FR Doc. 2010–31997 Filed 12–20–10; 8:45 am]

BILLING CODE 6712–01–P