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]

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