by the International Plant Protection Convention of the United Nations' Food and Agriculture Organization and is incorporated by reference in § 300.5 of this chapter. APHIS will publish a notice in the **Federal Register** and maintain on an APHIS Web site a list of the specific areas that are approved as areas in which Karnal bunt is not known to occur in order to provide the public with current, valid information. Areas listed as being free from Karnal bunt are subject to audit by APHIS to verify that they continue to merit such listing.

(c) *Handling, inspection and phytosanitary certificates.* Any articles described in paragraph (a)(2) of this section that are from a region listed in paragraph (b)(1) of this section may be imported into the United States subject to the following conditions:

(1) The articles must be from an area that has been recognized, in accordance with paragraph (b) of this section, to be an area free of Karnal bunt, or the articles have been tested and found to be free of Karnal bunt;

(2) The articles have not been commingled prior to arrival at a U.S. port of entry with articles from areas where Karnal bunt is known to occur;

(3) The articles offered for entry must be made available to an inspector for examination and remain at the port until released, or authorized further movement pending release, by an inspector; and

(4) The articles must be accompanied by a phytosanitary certificate issued by the national plant protection organization of the region of origin that includes the following additional declaration: ''These articles originated in an area where Karnal bunt is not known to occur, as attested to either by survey results or by testing for bunted kernels or spores.''

(d) *Treatments.* (1) Prior to entry into the United States, the following articles must be cleaned by removing any soil and plant debris that may be present.

(i) All conveyances and mechanized harvesting equipment used for storing and handling wheat, durum wheat, or triticale that tested positive for Karnal bunt based on bunted kernels.

(ii) All grain storage and handling equipment used to store or handle seed that has tested spore positive or grain that has tested bunted-kernel positive.

(iii) All seed-conditioning equipment used to store or handle seed that has tested spore-positive.

(2) Articles listed in paragraphs (d)(1)(i) and (d)(1)(ii) of this section will require disinfection in addition to cleaning prior to entry into the United States if an inspector or an official of the plant protection organization of the country of origin determines that disinfection is necessary to prevent the spread of Karnal bunt. Disinfection is required for all seed conditioning equipment covered under paragraph (d)(1)(iii) prior to entry into the United States.

(3) Items that require disinfection prior to entry into the United States must be disinfected by one of the methods specified in paragraphs (d)(3)(i) through (d)(3)(iii) of this section, unless a particular treatment is designated by an inspector or by an official of the plant protection organization of the country of origin:

(i) Wetting all surfaces to the point of runoff with a 1.5 percent sodium hypochlorite solution and letting stand for 15 minutes, then thoroughly washing down all surfaces after 15 minutes to minimize corrosion;

(ii) Applying steam to all surfaces until the point of runoff, and so that a temperature of 170 °F is reached at the point of contact; or

(iii) Cleaning with a solution of hot water and detergent, applied under pressure of at least 30 pounds per square inch, at a minimum temperature of 170 °F.

Done in Washington, DC, this 27th day of February 2004.

Bill Hawks,

Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 04–4723 Filed 3–2–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 314

[Docket No. 2004N–0087]

Generic Drug Issues; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Request for comments.

SUMMARY: The Food and Drug Administration (FDA) is requesting public comments on whether additional regulatory actions should be taken concerning the approval of abbreviated new drug applications (ANDAs). The agency is asking for comments because of recent statutory changes. The agency is not proposing any regulatory changes in this notice. The purpose of this notice is to identify a number of issues that the agency would like interested persons to address and to give interested persons an opportunity to submit comments on possible actions.

DATES: Submit written or electronic comments by May 3, 2004.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 200857. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Elaine Tseng, Office of Regulatory Policy (HFD–7), Food and Drug Administration, 5515 Security Lane, Rockville, MD 20852, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

On December 8, 2003, President Bush signed into law the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Public Law 108–173). Title XI of MMA made changes to section 505(a), (b), and (j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 505(a), (b), and (j). In particular, Title XI of MMA made changes to the approval procedures for ANDAs.

FDA is considering what additional regulatory steps, if any, are warranted in light of the statutory changes. The specific portions of the statute for which FDA seeks comment are Title XI of MMA's provisions concerning the 30-month stay of effectiveness period, 180-day exclusivity, and bioavailability and bioequivalence. FDA seeks comments identifying issues contained in the relevant portions of Title XI of MMA, along with any suggestions for how to resolve those issues. FDA will consider these comments in assessing what regulatory actions might be appropriate.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written of electronic comment regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets at 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.

Dated: February 27, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–4775 Filed 3–1–04; 8:45 am]

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