and E airspace designations listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle 1, section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in subtitle VII, part A, subpart 1, section 40103, Sovereignty and use of airspace. Under that section, the FAA is charged with prescribing regulations to ensure the safe and efficient use of the navigable airspace. This regulation is within the scope of that authority because it proposes changes to Class D and E airspace that remain sufficient in size to contain aircraft executing instrument procedures at Allen AAF and represents the FAA's continuing effort to safely and efficiently use the navigable airspace.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS D AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9P, *Airspace Designations and Reporting Points*, dated September 1, 2006, and effective September 15, 2006, is to be amended as follows:

* * * * *

Paragraph 5000 General.

* * * * *

AAL AK D Delta Junction, AK [Revised]

Allen AAF, AK
(Lat. 63°59″40′ N., long. 145°43″18′ W.)
Big Delta VORTAC
(Lat. 64°00″16′ N., long. 145°43″02′ W.)
Delta Junction Airport (D66), AK
(Lat. 64°03″02′ N., long. 145°43″02′ W.)

That airspace extending upward from the surface to and including 3,800 feet MSL within a 6.3-mile radius from Allen AAF; excluding the portion within the boundary of restricted areas R2202A and R2202C, and excluding that airspace below 700 feet above the surface contained within an area from an East/West line 1/2-mile south of the Delta Junction Airport (D66), extending from 1 mile east of the Richardson Highway to 1 mile west of the Delta River, thence northwest and parallel to the Richardson Highway and the Delta River, to the 6.3-mile radius from Allen AAF. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

Paragraph 6000 General.

* * * * *

AAL AK E2 Delta Junction, AK [Revised]

Allen AAF, AK
(Lat. 63°59″40′ N., long. 145°43″18′ W.)

Within an area from an East/West line ½-mile south of the Delta Junction Airport (D66), extending from 1 mile east of the Richardson Highway to 1 mile west of the Delta River, thence northwest and parallel to the Richardson Highway and the Delta River, to the 6.3-mile radius from Allen AAF. This Class E2 airspace area is effective only when Class D airspace is activated.

Paragraph 6004 Class E airspace areas designated as an extension to a Class D surface area.

* * * * *

AAL AK E4 Delta Junction, AK [Revised]

Allen AAF, AK
(Lat. 63°59″40′ N., long. 145°43″18′ W.)
Big Delta VORTAC
(Lat. 64°00″16′ N., long. 145°43″02′ W.)

The airspace extending upward from the surface within 3 miles north and 2.6 miles south of the 039° radial of the Big Delta VORTAC extending from the 6.3-mile radius from Allen AAF to 10.3 miles northeast of Allen AAF.

Paragraph 6005 Class D airspace extending upward from 700 feet or more above the surface of the earth.

* * * * *

AAL AK E5 Delta Junction, AK [Revised]

Allen AAF, AK
(Lat. 63°59″40′ N., long. 145°43″18′ W.)
Big Delta VORTAC
(Lat. 64°00″16′ N., long. 145°43″02′ W.)

That airspace extending upward from 700 feet above the surface within an 8.6-mile radius of Allen AAF, and within 3 miles north and 2.6 miles south of the 039° radial of the Big Delta VORTAC extending from the 8.6-mile radius from Allen AAF, to 10.3 miles northeast of Allen AAF; excluding the portion within restricted areas 2202A and R2202C.

* * * * *

Issued in Anchorage, AK, on October 23, 2006.

Anthony M. Wylie,

Director, Alaska Flight Service Information Office.

[FR Doc. E6–18264 Filed 10–30–06; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 20, 201, 207, 314, 330, 514, 515, 601, 607, 610, and 1271

[Docket No. 2005N–0403]

RIN 0910–AA49

Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs; Public Meeting; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; notice of public meeting and extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to discuss the proposed changes to the National Drug Code (NDC) system contained in the agency's proposed rule governing drug establishment registration and drug listing. The proposed rule appeared in the **Federal Register** of August 29, 2006 (71 FR 51276). In addition, in response to requests for an extension, FDA is extending to January 26, 2007, the comment period for the proposed rule to

provide interested parties additional time to submit comments.

DATES: The public meeting will be held on December 11, 2006, from 9 a.m. to 4 p.m. Register to attend the meeting by November 24, 2006. Submit written or electronic comments for consideration at the meeting and requests to speak by November 24, 2006. Submit written or electronic comments on the proposed rule and this notice by January 26, 2007.

ADDRESSES: The public meeting will be held at FDA, Center for Drug Evaluation and Research Advisory Committee Conference Room, 5630 Fishers Lane, rm. 1066, Rockville, MD 20852.

You may submit comments, identified by Docket No. 2005N–0403 and RIN number 0910–AA49, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

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.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name and Docket No(s). and Regulatory Information Number (RIN) for this rulemaking. All comments received may be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For additional information on submitting comments, see the ''Request for 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.fda.gov/ohrms/dockets/default.htm* and insert the docket number(s), found in 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: Lakshmi Cherukuri, Center for Drug Evaluation and Research (HFD–330), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–8924, E-mail: *Lakshmi.Cherukuri@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 29, 2006 (71 FR 51276), FDA published a proposed rule entitled ''Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs that are Regulated Under a Biologics License Application, and Animal Drugs'' (proposed rule). The proposed revisions would reorganize, consolidate, clarify, and modify current regulations concerning who must register establishments and list human drugs, human drugs that are also biological products (including vaccines and allergenic products), and/or human cells, tissues, and cellular and tissue-based products, and animal drugs.

The proposed rule would make certain changes to the NDC system and add a requirement that the appropriate NDC number appear on the labels of all drugs subject to the listing requirements. The NDC number is a widely used identifier for drugs. It is a unique 10–digit number consisting of 3 segments: The labeler code, the product code, and the package code. NDC numbers are an important, standardized identification system for drug products used in data or claims processing and for a variety of other purposes where identification of drug products is essential. For more information regarding the NDC number, how it originated, and how it is used, see the preamble of the proposed rule (71 FR 51276 at 51295 to 51296). In the proposed rule, FDA is not proposing to change the format of the NDC number (although comments are welcome on this topic), but is proposing to change the processes for assigning and displaying the NDC number. FDA's proposed changes to the NDC number are described in detail in section IV.C of the preamble of the proposed rule (71 FR 51276 at 51295 through 51306).

II. The Public Meeting

A. Request for a Public Meeting on NDC-Related Issues

In a letter dated October 20, 2005, the Healthcare Distribution Management Association (HDMA), a trade association representing drug distributors, requested that before publishing the proposed rule, FDA hold a public meeting on issues related to changes to the NDC system. FDA responded by letter dated December 14, 2005, that we planned to hold a public meeting on NDC changes during the comment period following publication of the proposed rule. We stated that doing so after the proposal was published would give interested parties the benefit of reviewing the agency's proposal prior to the meeting, which would facilitate more focused comments during the meeting on issues raised in the proposed rule.

B. Scope of the Public Meeting

As requested, we are holding a public meeting to discuss changes to the NDC system contained in the proposed rule. We emphasize that discussion at this public meeting will be limited to NDC-related issues and will not include any other registration or listing issues. Persons wishing to comment on other aspects of the proposed rule should do so by submitting their comments, in writing, as directed in the proposal.

We anticipate that discussions will include presentations from FDA personnel, invited speakers, and members of the public. We invite discussion of NDC-related topics raised in the proposed rule, including the following:

1. The proposed requirement that human-readable NDC numbers appear on the labels of drugs subject to the drug listing requirements (see 71 FR 51276 at 51297).

2. The proposed requirement that the ''appropriate NDC number'' that must appear on the labels of drugs is the NDC number of the last manufacturer, repacker or relabeler (including a drug product salvager who repacks or relabels the drug), or private label distributor responsible for the drug immediately before it is received by the wholesaler or retailer (see 71 FR 51276 at 51297 to 51298).

3. The proposed requirement that the human-readable NDC number be immediately preceded by the prefix ''NDC'' (see 71 FR 51276 at 51298).

4. The proposal to designate the responsibility of assigning the NDC number to FDA (see 71 FR 51276 at 51299).

5. The proposed prohibitions against using an NDC number to represent a different drug than the drug to which the NDC number was assigned, and against using a different NDC number if marketing is resumed for a drug that was discontinued earlier (see 71 FR 51276 at 51305).

6. The proposal to exempt from public disclosure the NDC number assigned to the drug immediately before the drug is received by the repacker or relabeler. The reason for the proposed exemption is that this information may disclose a business relationship between the manufacturer, repacker, relabeler, or drug product salvager and the business from which they obtained the drug, and may constitute commercial or financial information that is exempt from public disclosure (see 71 FR 51276 at 51320).

7. The possibility of adding one or more digits to the NDC code in the future (see 71 FR 51276 at 51300).

C. Registration, Agenda, and Transcript

There is no fee to register for the meeting, but registration is required and space is limited. Interested parties are therefore encouraged to register early. Limited visitor parking is available for a fee, and the Twinbrook Metro Stop is within walking distance of the meeting site. Early arrival is encouraged, as there will be security screening. You will be asked for government-issued picture identification by the security officers. If you need special accommodations due to a disability, please include this information when registering.

Registration for General Attendees. Registration is required to attend the public meeting. If you wish to attend the meeting, you must register by November 24, 2006, via e-mail to: *CDER_330CATS@cder.fda.gov*. Please indicate ''National Drug Code (NDC) system'' in the SUBJECT line and provide complete contact information for each attendee (including name, title, affiliation, e-mail address, and phone number(s)). Upon receipt and review for adequacy of information, an e-mail will be sent to confirm registration.

Registration for Speaking Attendees. If you wish to speak at the meeting, you must register by November 24, 2006, via e-mail to: *CDER_330CATS@cder.fda.gov*. Please indicate ''Speaker-National Drug Code (NDC) system'' in the SUBJECT line. When registering, speakers must provide the following information: (1) The NDC-related topic or issue to be addressed; (2) the speaker's name, title, company or organization, address, phone number, and e-mail address; and (3) the approximate length of time requested to speak. We encourage consolidation of like minded presentations to enable a broad range of views to be presented.

Agenda and Transcript. The agenda for the public meeting will be available on FDA's Center for Drug Evaluation and Research (CDER) Web site at: *www.fda.gov/cder/ndc/database/default.htm*. After the meeting, the agenda, presentations, and transcript will be placed on file in the Division of Dockets Management under Docket No. 2005N–0403 and on CDER's Web site identified previously.

Copies of the transcript may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 20 working days after the meeting at a cost of 10 cents per page, or on compact disc at a cost of $14.25 each. You may also examine the transcript at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and on the Internet at *http://www.fda.gov/ohrms/dockets/default.htm*.

III. Extension of the Comment Period for the Proposed Rule

By letter dated September 25, 2006, the Compressed Gas Association and the Gases and Welding Distributors Association requested an extension of 60 days to comment on the proposed rule because their member companies do not have sufficient time to evaluate the economic impact of the proposal and report their findings to FDA. By letter dated September 26, 2006, the Animal Health Institute (AHI) also requested a 60–day extension of the comment period to provide AHI additional time to review the proposed rule, analyze the impact on its industry, and provide comments to FDA. In addition, by letter dated October 12, 2006, the Consumer Healthcare Products Association (CHPA) requested a 60–day extension of the comment period to provide CHPA additional time to obtain and review opinions and responses from its member companies.

FDA has considered these extension requests and is extending the comment period to January 26, 2007. We believe that extending the comment period is reasonable in light of the complexity and scope of the issues in the proposed rule and that it will not significantly delay resolution of this rulemaking.

IV. Request for Comments

We are interested in obtaining public comment on the NDC-related issues identified in this document. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on this document and the proposed rule (see **DATES**). Submit two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with Docket No. 2005N–0403. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 25, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–18310 Filed 10–30–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. 2006N-0362]

General and Plastic Surgery Devices; Reclassification of the Absorbable Hemostatic Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify the absorbable hemostatic device intended to produce hemostasis from class III (premarket approval) into class II (special controls). FDA is proposing this reclassification in accordance with the Federal Food, Drug, and Cosmetic Act (the act). Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance document that would serve as the special control if FDA reclassifies this device.

DATES: Submit written comments by January 29, 2007. See section X of this document for the proposed effective date of a final rule based on this proposed rule.

ADDRESSES: You may submit comments, identified by Docket No. 2006N–0362, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways: