

# Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 15

[Docket No. FDA-2018-N-2610]

#### Future Format of the National Drug Code; Public Hearing; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notification of public hearing; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is announcing a public hearing and an opportunity for public comment on the future format of the National Drug Code (NDC). FDA is seeking input from a variety of stakeholders through comments and responses to FDA questions included in this notice and associated web content to be published ahead of the hearing. The questions are intended to allow FDA to obtain stakeholders' perspectives on the impact of any future changes made to the length and format of the NDC.

**DATES:** The public hearing will be held on November 5, 2018, from 8:30 a.m. to 5 p.m. The hearing may be extended or end early depending on the level of public participation. Persons seeking to attend or present at the public hearing must register by October 15, 2018. Electronic or written comments will be accepted after the public hearing until January 5, 2019.

**ADDRESSES:** The public hearing will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503 Section B and C), Silver Spring, MD 20993-0002. Entrance for the public hearing participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to <https://www.fda.gov/AboutFDA/>

[WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm](https://www.fda.gov/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm).

You may submit comments as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

**Instructions:** All submissions received must include the Docket No. FDA-2018-N-2610 for "Future Format of the National Drug Code; Public Hearing; Request for Comments." Received comments, those filed in a timely manner (see **DATES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at

<https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Leyla Rahjou-Esfandiary, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2262, Silver Spring, MD 20993, 301-796-3185, [NDCPublicHearing@fda.hhs.gov](mailto:NDCPublicHearing@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

The NDC is an FDA standard for uniquely identifying drugs in the United States. Currently, NDCs assigned by FDA contain 10 digits. As described in § 207.33(b) (21 CFR 207.33(b)), NDCs consist of three segments: the labeler code, the product code, and the package code. At some point in the next 10 to 15 years, NDC formatting will need to be updated to accommodate longer NDCs because new labelers are continually entering the U.S. market. In 2016, when FDA published the “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, Final Rule” FDA stated that when it runs out of 5-digit labeler codes, it will begin assigning 6-digit labeler codes. (81 FR 60170, August 31, 2016). As a result, FDA will add two new 11-digit NDC formats to accommodate the longer labeler codes. However, FDA acknowledged that some stakeholders expressed an interest in FDA moving to a single, standard format for NDCs and announced that it would initiate a public discussion of future formatting options (81 FR 60170 at 60187). Because of the widespread use and dependency on NDCs in prescribing, dispensing, reimbursement, safety, clinical management, supply chain management, and pharmaceutical manufacturing and labeling systems, the Agency is holding a public hearing and requesting comments from stakeholders on the impact of the transition to 6-digit labeler codes.

Section 510 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360) requires each registered drug establishment to provide FDA with a current list of all drugs manufactured, prepared, propagated, compounded, or processed by the establishment for commercial distribution. Drug products are identified and reported using the NDC.

The NDC for each listed drug in the United States is a unique 10-digit, 3-

segment number. The 3 segments of NDC include the labeler code, product code, and package code. A labeler code is a unique 4-, 5-, or (in the future) 6-digit number assigned by FDA that identifies the manufacturer, repacker, relabeler, or private label distributor of the drug. The second segment, the product code, identifies a specific strength, dosage form, and formulation of a drug manufactured, repackaged, relabeled, or distributed by the labeler. The third segment, the package code, identifies package sizes and types. Different package codes only differentiate between different quantitative and qualitative attributes of the product packaging. Both the product and package codes are proposed by persons submitting drug listing information. FDA will assign a proposed NDC if it has not been used previously, is not currently in use, and has not been reserved for future assignment to a different product. The NDC for a given drug is currently in one of the following configurations (with each number representing the number of digits in that segment): 4–4–2, 5–3–2, or 5–4–1.

According to current regulations, labeler codes may consist of 4, 5, or 6 digits (§ 207.33(b)(1)). Currently, 5-digit labeler codes are being assigned by FDA. A 5-digit labeler code format provides FDA with 90,000 labeler codes that could be assigned to drug manufacturers and private label distributors ranging from 10,000 to 99,999. Based on current assignment rates, FDA anticipates that it will run out of 5-digit labeler codes in approximately 15 years. FDA will begin assigning 6-digit labeler codes at some point in the future due to exhaustion of 5-digit labeler codes. Moving up to 6-digit labeler codes will expand NDCs to 11 digits and, per regulation, allows for two additional NDC configurations: 6–3–2 and 6–4–1, for a total of five possible NDC configurations (including the three 10-digit NDC configurations).

The Health Insurance Portability and Accountability Act (HIPAA) (Pub. L. 104–191) contains provisions calling for

the administrative simplification “of the national standards for electronic health care transactions and code sets, unique health identifiers, and security”<sup>1</sup> and specifically references the NDC. In its implementation of these rules, in August 2000, the Department of Health and Human Services (HHS) published a final rule on standards for electronic transactions that established NDC numbers as the standard medical data code set for reporting drugs and biologics in all standard transactions under HIPAA (65 FR 50312). If a HIPAA-covered transaction includes a drug, the NDC is required to be a part of the medical code data set (see 45 CFR subpart J 162.1002(a)(3)). However, in the preamble to the HIPAA regulations, HHS stated that it was adopting a uniform 11-digit format to conform with customary practice used in computer systems (65 FR 50312 at 50329). The HIPAA standard 11-digit NDC format is standardized such that the labeler code is always 5 digits, the product code is always 4 digits, and the package code always 2 digits. To convert a 10-digit NDC to an 11-digit HIPAA standard NDC, a leading zero is added to the appropriate segment to create the 11-digit configuration as defined above.

When FDA moves to a 6-digit labeler code, although these new 11-digit native NDC<sup>2</sup> configurations will have the same number of digits as required by the HIPAA standards, they will not be in the same format.<sup>3</sup> Additionally, some of the systems that utilize HIPAA standard 11-digit NDCs<sup>4</sup> do not use hyphens to separate the segments which, as illustrated below, will result in some 11-digit native NDCs being indistinguishable from HIPAA standard 11-digit NDCs. Therefore, to ensure unhyphenated NDCs are distinguishable, FDA anticipates that the HIPAA standards, and other code sets that currently require 10-digit native NDCs to be converted to 11-digit NDCs, will likely be updated in some manner.

TABLE 1—NDC CONVERSION EXAMPLE

Native NDC format	Converted NDC format		
	10-digit hyphenated	11-digit converted (hyphenated)	11-digit converted (unhyphenated)
Native 10-digit (5–3–2) .....	10010–001–01	10010–0001–01	10010000101

<sup>1</sup> See <http://www.hhs.gov/ocr/privacy/hipaa/administrative/index.html> (last accessed July 3, 2017).

<sup>2</sup> NDCs in the format and with the digits assigned by FDA are referred to as *native NDCs*.

<sup>3</sup> An 11-digit native NDC will have an extra labeler code digit but will be short a digit in either the product code or package code.

<sup>4</sup> NDCs that contain additional digits necessary to comply with HIPAA standards are referred to as *Converted NDCs*.

TABLE 1—NDC CONVERSION EXAMPLE—Continued

Native NDC format	Converted NDC format		
	10-digit hyphenated	11-digit converted (hyphenated)	11-digit converted (unhyphenated)
Native 11-digit (6–3–2) .....	.....	100100–001–01	10010000101

**II. Purpose and Scope of the Hearing**

The purpose of this public hearing is to obtain and discuss stakeholder feedback on the future format of NDCs. FDA is seeking information on the following topics:

1. The impact of transitioning from a 5-digit labeler code to a 6-digit labeler code, including the business, economic, information technology, and medical/clinical practice impacts, and its impact on the safety and security of drug products.
2. Issues associated with the current lack of NDC uniformity in the marketplace.
3. What should FDA consider as it explores any further changes or expansion to the format or length of the NDC?
4. How to best transition to a new format for the NDC.

To facilitate stakeholder feedback, some options for discussion and questions will be posted in the docket and on FDA’s website at <https://www.fda.gov/Drugs/NewsEvents/ucm574488.htm> at least 30 days prior to the hearing. These options and questions are not meant to be exhaustive. We encourage interested stakeholders to address these and/or other issues related to the formatting of NDCs. FDA encourages stakeholders to provide the rationale and basis for their comments, including any available data and information, and any underlying assumptions. For example, to provide context associated with a stakeholders response, FDA also is interested in the following information within the submission or testimony.

1. How would you describe your business or area of focus (e.g., payor, hospital, health care practitioner, benefit manager or administrator, pharmacy, manufacturer, repackager, wholesale distributor, third-party logistics provider, drug compendia, standard setting organization, government entity)?
2. How do you or your members use the NDC?
3. What challenges does your organization or your members face with the current NDC and how do you overcome these challenges?

4. What changes, if any, would you or your members need to make to your systems to accommodate the 6-digit labeler code or other larger NDC formats?

**III. Registration**

*Registration and Requests for Oral Presentations*

The FDA Conference Center at the White Oak location is a Federal facility with security procedures and limited seating. Attendance is free and early registration is recommended. Individuals who wish to attend must register on or before October 15, 2018, at <https://www.fda.gov/Drugs/NewsEvents/ucm574488.htm> and provide complete contact information, including name, title, affiliation, email, and phone number. Those without internet access may register by contacting Leyla Rahjou-Esfandiary at 301–796–3185. FDA may allow onsite registration if space is available. If registration reaches maximum capacity, FDA will post a notice closing registration at <https://www.fda.gov/Drugs/NewsEvents/ucm574488.htm>.

This hearing will include public comment sessions. Individuals who wish to present during a public comment session at the public hearing must register as noted at <https://www.fda.gov/Drugs/NewsEvents/ucm574488.htm> and identify the topics or questions (see section II) they wish to address in their presentation and the stakeholder group they best associate with, if any, to help FDA organize the presentations. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time for a joint presentation.

FDA will do its best to accommodate requests to present during the public comment session and will determine the amount of time allotted for each oral presentation and the approximate time that each oral presentation is scheduled to begin. FDA will notify registered presenters of their scheduled times and make available an agenda and background material at <https://www.fda.gov/Drugs/NewsEvents/ucm574488.htm> on or before October 22, 2018. Once FDA notifies registered

presenters of their scheduled times, presenters should submit an electronic copy of their presentation to [NDCPublicHearing@fda.hhs.gov](mailto:NDCPublicHearing@fda.hhs.gov) on or before October 29, 2018.

If you need special accommodations because of a disability, please send an email to [NDCPublicHearing@fda.hhs.gov](mailto:NDCPublicHearing@fda.hhs.gov) at least 7 days before the hearing.

*Streaming Webcast of the Public Hearing*

A link to the live webcast of this public hearing will be available at <https://www.fda.gov/Drugs/NewsEvents/ucm574488.htm> on the day of public hearing. A video record of the public hearing will be available at <https://www.fda.gov/Drugs/NewsEvents/ucm574488.htm> following the hearing.

**IV. Notice of Public Hearing Under 21 CFR Part 15**

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The hearing will be conducted by a presiding officer, who will be accompanied by FDA senior management from the Office of the Commissioner and the relevant centers/offices.

Under § 15.30(f), the hearing is informal and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation. At their discretion, the presiding officer(s) may permit questions to be submitted from the audience for response by FDA or other persons attending the hearing (§ 15.30(e)). Public hearings under part 15 are subject to FDA’s policy and procedures for electronic media coverage of FDA’s public administrative proceedings (21 CFR part 10, subpart C). Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA’s public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b) (see *Transcripts*). To the extent that the

conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

#### Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at <https://www.regulation.gov>. It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's website at <https://www.fda.gov>.

Dated: July 31, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-16807 Filed 8-6-18; 8:45 am]

**BILLING CODE 4164-01-P**

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## DEPARTMENT OF STATE

### 22 CFR Chapter I

#### 48 CFR Chapter 6

[Public Notice: 10489]

### Reducing Regulation and Public Burden, and Controlling Cost

**AGENCY:** Department of State.

**ACTION:** Request for comments.

**SUMMARY:** As part of its continuing implementation of Executive Order 13771, "Reducing Regulation and Controlling Regulatory Costs," issued by the President on January 30, 2017, the Department of State (the Department) is seeking comments and information from interested parties to assist the Department in identifying existing regulations, paperwork requirements and other regulatory obligations that can be modified or repealed, consistent with law, to achieve meaningful burden reduction while continuing to achieve the Department's statutory obligations.

**DATES:** Written comments and related material must be received on or before September 6, 2018.

**ADDRESSES:** You may submit comments by email to the following address: [RegsReform@state.gov](mailto:RegsReform@state.gov).

**FOR FURTHER INFORMATION CONTACT:**

Alice Kottmyer, Attorney-Adviser, 202-647-2318; or Janet Freer, Director of the Office of Directives Management. Both can be reached at [RegsReform@state.gov](mailto:RegsReform@state.gov).

**SUPPLEMENTARY INFORMATION:** On January 30, 2017, President Trump

issued Executive Order 13771, Reducing Regulation and Controlling Regulatory Costs. Under that Executive Order, for every one new regulation issued, at least two prior regulations must be identified for elimination, and the cost of planned regulations must be prudently managed and controlled through a budgeting process. On February 24, 2017, the President issued Executive Order 13777, Enforcing the Regulatory Reform Agenda. That Executive Order directs agencies to take specific steps to identify and alleviate unnecessary regulatory burdens placed on the American people. We are seeking comments on Department regulations, guidance documents, and collections of information that you believe should be removed or modified to alleviate unnecessary burdens. The Department is also requesting economic data to support any proposed changes.

#### The Regulatory Reform Task Force

Executive Order 13777 directs agencies to designate a Regulatory Reform Officer (RRO) and to establish a Regulatory Reform Task Force (RRTF). The Deputy Secretary of State is the RRO. Other RRTF members include senior officials in the Department's primary regulatory bureaus (Bureaus of Consular Affairs, Educational and Cultural Affairs, Political-Military Affairs, and Administration), as well as other Department officials with expertise in legal requirements, planning and budget.

One of the duties of the RRTF is to evaluate existing regulations and make recommendations to the Secretary regarding their repeal, replacement, or modification. Executive Order 13777 further directs that the RRTF attempt to identify regulations that:

- Eliminate jobs, or inhibit job creation;
- Are outdated, unnecessary, or ineffective;
- Impose costs that exceed benefits;
- Create a serious inconsistency or otherwise interfere with regulatory reform initiatives and policies;
- Are inconsistent with the requirements of section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note), or the guidance issued pursuant to that provision, in particular those regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard of reproducibility; or

- Derive from or implement Executive Orders or other Presidential directives that have been subsequently rescinded or substantially modified.

Section 3(e) of the Executive Order calls on the RRTF to "seek input and other assistance, as permitted by law, from entities significantly affected by Federal regulations, including State, local, and tribal governments, small businesses, consumers, nongovernmental organizations, and trade associations" on regulations that meet some or all of the criteria above. The Department sought input in 2017 (see 82 FR 32493), and again solicits your comments.

#### Location of Department Regulations

Existing Department of State regulations can be found in the Code of Federal Regulations (CFR) in two places:

- 22 CFR Chapter I (parts 1 through 199), which contains rules governing Department operations; and
- 48 CFR Chapters VI (part 600), which contains the Department's Acquisition Rules.

In addition, guidance regarding Department grants can be found at 2 CFR chapter VI.

You may view the most up-to-date versions of these authorities in the electronic CFR, located at [www.ecfr.gov](http://www.ecfr.gov).

#### Location of Department Guidance

Department guidance that relates to the missions of the rulemaking bureaus (identified above) can be found in a number of locations on the state.gov public website. The Department is interested in comments regarding any of the guidance located on its public site. For your convenience, the following sites cover specific missions:

- For Consular Affairs, including passports and visas, please visit <https://travel.state.gov>.
- For Educational and Cultural Affairs, including the Exchange Visitor Program, please visit <https://exchanges.state.gov/>.
- For Defense Trade issues, please visit: <https://www.pmdetc.state.gov/>.

You are invited to provide comment on any guidance published by the Department that you feel should be considered for modification or elimination, in accordance with E.O. 13777.

#### Location of the Department's Unified Agenda Submission

The Department's most current submission to the Unified Agenda of Regulatory and Deregulatory Actions is located at <https://www.reginfo.gov/public/do/eAgendaMain>. Select "Department of State" from the dropdown menu. The Agenda consists of regulatory and de-regulatory actions either in progress or contemplated by the Department. The rules are identified