appropriate. If sending information directly to the International Branch, send it to ATTN: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone (425) 227–2125; fax (425) 227–1149. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(k) Related Information

(1) Refer to MCAI European Aviation Safety Agency Airworthiness Directive 2012–0042, dated April 10, 2012; and Airbus Mandatory Service Bulletin A310–57–2100, Revision 01, dated February 3, 2012; for related information.

(2) For service information identified in this AD, contact Airbus SAS–EAW (Airworthiness Office), 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* Internet *http://www.airbus.com.* You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on November 9, 2012.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2012–27999 Filed 11–16–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 801

[Docket No. FDA–2011–N–0090]

RIN 0910–AG31

Unique Device Identification System

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its July 10, 2012, proposed rule (77 FR 40736) to establish a unique device identification system as required by recent amendments to the Federal Food, Drug, and Cosmetic Act (the FD&C Act). On July 9, 2012, the Food and Drug Administration Safety and Innovation Act (FDASIA) was signed into law; section 614 of FDASIA amends the FD&C Act in ways that require modification of the timeframe for implementation of the proposed rule's requirements as they apply to devices that are implantable, life-saving (life-supporting), or life-sustaining.

DATES: Submit either electronic or written comments on the amendment to the Proposed Rule by December 19, 2012. See section VII for the proposed effective dates of a final rule based on the amended proposed rule.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2011–N–0090 and/or RIN Number 0910–AG31, 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 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, Docket Number, and Regulatory Information Number (RIN) 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 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: Jay Crowley, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–5995, email: *cdrhudi@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, FDASIA was signed into law (Pub. L. 112–144). On July 10, 2012, FDA published a proposed rule to establish a unique device identification system, as required by section 519(f) of the FD&C Act (21 U.S.C. 360i(f)). Section 614 of FDASIA amends section 519(f) of the FD&C Act in ways that require modification of the timeframe for implementation of the proposed rule's requirements as they apply to devices that are implantable, life-saving (life-supporting), or life-sustaining. This document explains how FDA is amending the July 10, 2012, proposed rule to meet the requirements of amended section 519(f) of the FD&C Act.

II. Description of the Proposed Rule

A. FDA's July 10, 2012, Proposed Rule

Our July 10, 2012, document provides a detailed description of the proposed rule. The proposed rule includes unique device identifier (UDI) labeling requirements (proposed for inclusion in 21 CFR part 801), requirements relating to issuing Agencies and submission of data to the Global Unique Device Identification Database (GUDID) (proposed new part 830), and conforming amendments to several existing FDA regulations. FDA proposed a phased implementation of the rule's requirements, with some requirements going into effect immediately after publication of a final rule, and other requirements going into effect 1 year, 3 years, 5 years, and 7 years after publication of a final rule. This phased implementation is summarized in the July 10, 2012, proposed rule by Table 7—Effective Dates of UDI Regulatory Requirements (77 FR 40736 at 40764).

B. Changes Required by the Enactment of FDASIA

Section 614 of FDASIA amends section 519(f) of the FD&C Act, the provision that requires FDA to establish a unique device identification system. Prior to the enactment of FDASIA, section 519(f) of the FD&C Act did not specify the date by which a proposed rule is required, did not identify any particular devices as requiring expedited implementation of UDI requirements, and did not specify timeframes for publication of a final rule. The FDASIA amendments to section 519(f) address each of those points. As amended by FDASIA, section

519(f) of the FD&C Act now requires that not later than December 31, 2012, the Secretary shall issue proposed regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number. Section 519(f) of the FD&C Act also requires that the Secretary shall finalize the proposed regulations not later than 6 months after the close of the comment period and shall implement the final regulations with respect to devices that are implantable, life-saving, and life sustaining not later than 2 years after the regulations are finalized, taking into account patient access to medical devices and therapies.

The change that has prompted amendment of FDA's proposed rule is the provision in the final sentence that requires ''final regulations with respect to devices that are implantable, life-saving, and life sustaining'' to be implemented within 2 years of finalization of the rule. (We refer to ''life-saving'' devices as ''life-supporting,'' as explained later in this document.). Thus we are amending our July 10, 2012, proposed rule by changing some of the proposed effective dates for requirements applicable to implantable, life-supporting, and life-sustaining devices, so that the requirements applicable to these devices will be effective no later than 2 years from finalization of the rule.

Under our July 10, 2012, proposed rule, all class III devices and all devices licensed under the Public Health Service Act (PHS Act) (42 U.S.C. 262) would be required to bear a UDI within 1 year of the date we publish a final rule; thus, this effective date does not need to be changed. Pursuant to amended section 519(f) of the FD&C Act, we are now proposing to require all other implantable, life-supporting, and life-sustaining devices (i.e., those that are not already subject to the 1-year effective date) to bear a UDI within 2 years following the publication of a final rule. (See proposed § 801.20(b)(2) as amended by this document.) Under our July 10, 2012, proposed rule, when a device is required to be labeled with a UDI, proposed § 830.300 would require the labeler of that device to submit information concerning the device to the GUDID. Consequently, the labelers of all implantable, life-supporting, and life-sustaining devices will be required to submit data to the GUDID within 2 years of the date we publish a final rule; see proposed § 801.20(b)(1) and (b)(2) as amended by this document.

Proposed § 801.50 would require direct marking of the UDI on the device itself for implantable devices, devices intended to be used more than once and that are intended to be sterilized before each use, and stand-alone software. We are now amending the proposed rule so that any such devices that fall into the categories specified by revised section 519(f) of the FD&C Act—devices that are implantable, life supporting, or life sustaining—would have to comply with § 801.50, establishing a system of unique device identification 2 years after publication of a final rule. FDA believes that the only devices subject to direct marking that fit within the device categories expressly referred to in revised section 519(f) of the FD&C Act are implantable devices and is assuming only implantable devices will be affected by the revised implementation date for the direct marking requirement. We welcome comments on whether any devices subject to the direct marking requirement under proposed § 801.50 other than implantable devices fit within the device categories in amended section 519(f) of the FD&C Act.

FDA interprets ''life-saving'' in section 519(f) of the FD&C Act, as amended by section 614 of FDASIA, to have the same meaning as ''life-supporting'' in other device provisions of the FD&C Act. Section 614 of FDASIA refers to devices that are ''implantable, life-saving, and life-sustaining.'' The device provisions of the FD&C Act do not use the term ''life-saving'' in any other instance, but in several instances refer to devices that are ''implantable, life sustaining, or life supporting.'' (See section 513(a) of the FD&C Act (21 U.S.C. 360c(a)) (definitions of class II and class III devices); section 519 (records and reports on devices, including adverse event reporting and device tracking); section 522 of the FD&C Act (21 U.S.C. 360l) (postmarket surveillance); and section 523 of the FD&C Act (21 U.S.C. 360m) (accredited persons).) In order for the language of our proposed UDI rule to be consistent with existing FDA regulations and the other provisions of the FD&C Act, in the amendments to the proposed regulations we use the term ''life-supporting'' instead of ''life-saving.'' FDA, the medical device industry, and the health care community are already familiar with the term ''life-supporting'' as applied to medical devices, which will facilitate FDA's implementation of the amended proposed rule.

A list of product codes for devices that FDA considers to be implantable, life-saving, and life-sustaining for purposes of section 614 of FDASIA, amending section 519(f) of the FD&C Act, is available in docket FDA–2011–N–0090 (Ref. 12).

FDA is not extending the comment period of the proposed rule, which closed on November 7, 2012. We do not believe that amending some of the proposed effective dates for certain categories of devices necessitates additional time to review the amended proposed rule and to submit comments to FDA.

C. How the Amendments Made by This Proposed Rule Will Affect the July 10, 2012, Proposed Rule

These amendments affect only implantable, life-supporting, or life-sustaining devices. With the exception of the change to the proposed effective date for the direct marking requirement, these amendments do not affect class III devices or devices licensed under the PHS Act because such devices would have to bear a UDI within 1 year of finalization under the July 10, 2012, proposed rule.

We are updating Table 7—Effective Dates of UDI Regulatory Requirements, of the July 10, 2012, proposed rule to reflect the revisions provided by this document; we have also corrected two citations within the table (citations to § 830.320 should have cited § 830.300). Updated table 7 appears in this document in section VI. Updated Proposed Effective Dates.

New table 8 of this document summarizes the effects of the amendments we are making to the July 10, 2012, proposed rule.

TABLE 8—EFFECTS OF THE AMENDMENTS TO THE JULY 10, 2012, PROPOSED RULE

Category of device	Effect of amendments to proposed rule
Class III implantable, life-supporting, and life-sustaining devices, and implantable, life-supporting, and life-sustaining devices licensed under the PHS Act.	No effect with respect to proposed requirement for device to bear UDI on the label and device package or proposed requirements for submission of data to the GUDID.

TABLE 8—EFFECTS OF THE AMENDMENTS TO THE JULY 10, 2012, PROPOSED RULE—Continued

Category of device	Effect of amendments to proposed rule
Class II implantable, life-supporting, and life-sustaining devices	Implantable devices would have to bear a UDI as a permanent marking on the device itself 1 year earlier than first proposed. Would have to bear a UDI on the label and device package and submit data to the GUDID 1 year earlier than first proposed.
Class I implantable, life-supporting, and life-sustaining devices, and implantable, life-supporting, and life-sustaining devices that have not been classified into class I, II, or III.	Implantable devices would have to bear a UDI as a permanent marking on the device itself 3 years earlier than first proposed. Would have to bear a UDI on the label and device package and submit data to the GUDID 3 years earlier than first proposed. Implantable devices would have to bear a UDI as a permanent marking on the device itself 5 years earlier than first proposed.

D. Request for Comments

This amendment announces changes to the proposed rule required by FDASIA. The comment period on the proposed rule closed on November 7, 2012. We request comments only on the changes discussed in this amendment to the proposed rule and may decline to consider other comments submitted to this docket.

III. Legal Authority for the Proposed Rule

Section 226 of the Food and Drug Administration Amendments Act (Pub. L. 110–85) (2007), amended the FD&C Act by adding a new section 519(f). This section provides for FDA to issue regulations establishing a unique device identification system for medical devices. In addition, section 510(e) of the FD&C Act (21 U.S.C. 360(e)) authorizes FDA to issue regulations to ''prescribe a uniform system for identification of devices'' and to require persons to ''list such devices in accordance with such system.'' Therefore, FDA is issuing the provisions of this proposed rule that would establish a unique device identification system under sections 510(e), 519(f), and 701(a) (21 U.S.C. 371(a)) of the FD&C Act (which provides FDA the authority to issue regulations for the efficient enforcement of the FD&C Act).

Devices for which there has been a failure or refusal to furnish any material or information required by or under section 519 of the FD&C Act respecting the device are misbranded under section 502(t)(2) of the FD&C Act (21 U.S.C. 352(t)(2)). The failure or refusal to furnish any material or information required by or under section 519 of the FD&C Act is a prohibited act under section 301(q)(1)(B) of the FD&C Act (21 U.S.C. 331(q)(1)(B)).

Section 701(a) of the FD&C Act gives FDA the authority to issue regulations for the efficient enforcement of the FD&C Act. By requiring a UDI to appear on the label of devices, and by establishing the GUDID, the proposed rule is designed to improve the accuracy and precision of adverse event reporting, as required by section 519(a) and (b) of the FD&C Act, which will enable FDA to more quickly and precisely identify device problems, such as safety and/or effectiveness concerns. Once a problem is identified, whether through improved reporting or otherwise, the presence of the UDI on the device label, packaging, in certain cases directly marked on the device itself, and in the GUDID will enable FDA to more efficiently and effectively respond, and protect the public health by addressing the problem using one or more of the regulatory tools that Congress has provided for this purpose, such as notification or mandatory recall under section 518 of the FD&C Act (21 U.S.C. 360h), tracking under section 519(e) of the FD&C Act, ensuring the adequacy of a voluntary recall with the assistance of reports of corrections and removals as required by section 519(g) of the FD&C Act, or seizing a device that is adulterated under section 501 of the FD&C Act (21 U.S.C. 351) and/or misbranded under section 502 of the FD&C Act. Thus, these provisions of the proposed rule are issued under the authority of these sections in addition to the broad authority of section 519(f) of the FD&C Act.

Section 510(j) of the FD&C Act requires listing information to be accompanied by, at minimum, the label, package insert, and a representative sampling of any other labeling for the device (see section 510(j)(1)(B)(ii)). For certain categories of devices, all labeling must be submitted (see section 510(j)(1)(A) and (j)(1)(B)(i) of the FD&C Act). We expect most of the information that would be required to be submitted to the GUDID (see proposed § 830.310), is information that appears on the device label or in the package insert, and is included in the information that is required to be submitted to FDA by section 510(j) of the FD&C Act.

The provisions of the proposed rule that would require UDIs to be included in various records and reports, allow the use of UDIs to identify devices subject to reports of corrections and removals and records of corrections of removals that are not required to be reported to FDA, and require reporting of UDIs in periodic reports for class III devices, are issued under the authority of sections 519 and 701(a) of the FD&C Act.

The provisions of the proposed rule that would amend the Quality System Regulation by requiring examination of the accuracy of the UDI as part of the scope of the labeling inspection, that the device history record include any UDI or universal product code (UPC), that complaint records include any UDI or UPC, and that the service report include an UDI or UPC, are issued under sections 520(f) (21 U.S.C. 360j(f)) and 701(a) of the FD&C Act.

The provisions of the proposed rule that would require the inclusion of UDIs on reports regarding tracked devices is authorized by sections 519(e) and 701(a) of the FD&C Act.

The provision of the proposed rule that would require that postmarket surveillance plans submitted to FDA include the device identifier of the devices involved is issued under sections 522 (21 U.S.C. 360*l*), and 701(a) of the FD&C Act.

Finally, the changes in proposed effective dates for devices that are implantable, life-saving, and life sustaining, are pursuant to the changes to section 519(f) of the FD&C Act made by section 614 of FDASIA.

IV. Analysis of Impacts

Our July 10, 2012, document summarizes the analysis of impacts of the proposed rule. The full analysis of impacts and findings that are presented in Preliminary Regulatory Impact Analysis (RIA) of the proposed rule remain unchanged (Ref. 10 of the July 10, 2012, proposed rule). However, we are amending our summary of costs to include the FDASIA requirement to

incorporate the revised implementation date of 2 years for devices that are implantable, life-supporting, and life-sustaining. The July 10, 2012, RIA and the Addendum to the RIA (new Ref. 13) are available at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/ucm309815.htm*.

We lack sufficient information to estimate the number of establishments that label life-supporting and life-sustaining devices and would be affected by the FDASIA requirement. Therefore, for this amended cost summary, we make a simplifying assumption that labelers of all class II devices would comply with the UDI requirements in year 2 instead of year 3 as initially specified under the proposed rule. Because the modified timeframe would advance the implementation date to directly mark implantable, life-supporting, and life-sustaining devices, we assume that labelers of class III devices that are implants would comply with the direct marking requirements in year 2 instead of year 3 as initially specified under the proposed rule. The effect of these simplifying assumptions might be to overstate the annualized costs for some labelers of class II devices that are not considered life-supporting or life-sustaining devices, and to underestimate the annualized costs for some labelers of class I devices that are considered life-supporting or life-sustaining devices.

The amended summary of the total costs of the proposed rule for all sectors is presented in the updated table 3 of this document. The total present value of domestic costs for all affected sectors would be about $554.8 million over 10 years with a 7 percent discount rate and $625.4 million at 3 percent. The total annualized costs over 10 years would be $73.8 million at 7 percent and $71.1 million at 3 percent. The total increase in annualized costs to domestic labelers compared to the proposed rule is about $5.4 million at 7 percent over 10 years.

UPDATED TABLE 3—SUMMARY OF THE ESTIMATED REGULATORY COSTS OF THE PROPOSED RULE

[2010 dollars] [1] [2]

Affected sectors	Total present value of cost over 10 years ($ million)		Total annualized costs over 10 years ($ million)	
	3 Percent	7 Percent	3 Percent	7 Percent
Domestic Labelers	$608.3	$540.2	$69.2	$71.9.
Issuing Agencies	$1.0	$0.9	$0.1	$0.1.
FDA	$16.1	$13.7	$1.8	$1.8.
Imports	Not quantified	Not quantified	Not quantified	Not quantified.
Total Domestic Cost of the Proposed Rule	$625.4	$554.8	$71.1	$73.8.

[1] Present value and annualized costs calculated at the beginning of the period.

[2] Domestic costs for labelers are revised to reflect FDASIA requirement that labelers of affected devices comply in year 2. However, FDA's revised estimate assumes that all class II devices would comply in year 2.

Updated table 1 (and identical updated table 4 of the proposed rule) presents the Regulatory Information Service Center (RISC) and Office of Information and Regulatory Affairs (OIRA) Combined Information System (ROCIS) accounting information under the assumption that labelers of all class II devices would comply with the UDI requirements in year 2 and that all labelers of class II implantable devices would comply with the direct marking requirements in year 2.

Updated Table 1.--Costs and Benefits, and Updated Table 4.--Economic Data: Costs and Benefits Accounting Statement (2010 dollars)

				Units			
Category	Primary Estimate	Low Estimate	High Estimate	Year Dollars	Discount Rate	Period Covered	Notes
Benefits							
Annualized Monetized $millions/year					7%		
					3%		
Annualized Quantified					7%		
					3%		
Qualitative	More accurate and prompt identification of device related adverse events would lead to more rapid action to reduce the incidence of the adverse events and to more effectively target and manage medical device recalls.						
Costs							
Annualized Monetized $millions/year	$73.8	$37.6	$110.0	2011	7%	10 years	Costs to foreign labelers are not included.
	$71.1	$36.3	$106.0	2011	3%	10 years	
Annualized Quantified					7%		
					3%		
Qualitative							
Transfers							
Federal Annualized Monetized $millions/year					7%		
					3%		
From/To	From:			To:			
Other Annualized Monetized $millions/year					7%		
					3%		
From/To	From:			To:			
Effects							
State, Local or Tribal Government: No effect							
Small Business: The proposed rule may have a significant economic impact on a substantial number of small entities that label medical devices.							
Wages: No effect							

V. Information Collection Requirements

The updates made by this proposed rule do not affect the estimate we previously provided regarding our July 10, 2012, proposed rule.

In accordance with section 3507(d) of the PRA (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to OMB. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain* (OMB Number 0910–0720) and is posted to the docket at *http://www.regulations.gov,* in docket FDA–2011–N–0090 (Ref. 11 of the proposed rule).

VI. Environmental Impact

FDA has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Updated Proposed Effective Dates

FDA updates Table 7—Effective Dates of UDI Regulatory Requirements, in our July 10, 2012, proposed rule as follows.

UPDATED TABLE 7—EFFECTIVE DATES OF UDI REGULATORY REQUIREMENTS

Effective date	Requirement
Immediately upon publication of a final rule.	Requests for an exception or alternative to UDI labeling requirements may be submitted pursuant to § 801.35.
	§§ 830.100–830.130 (subpart C of part 830, concerning accreditation of issuing Agencies) and § 830.10 (incorporation by reference of certain standards) go into effect. This will allow applications for accreditation as an issuing Agency to be submitted to FDA immediately.
One year after publication of a final rule.	Dates on medical device labels must be formatted as required by § 801.18.
	The label and package of class III medical devices and devices licensed under the PHS Act must bear a UDI. § 801.20(b)(1).
	Data for class III devices and devices licensed under the PHS Act that are required to be labeled with a UDI must be submitted to the GUDID data base. § 830.300.
Two years after publication of a final rule.	The label and package of implantable, life-supporting, and life-sustaining devices that are not class III devices or licensed under the PHS Act must bear a UDI. § 801.20(b)(2).
	Data for implantable, life-supporting, and life-sustaining devices that are not class III devices or licensed under the PHS Act and that are required to be labeled with a UDI, must be submitted to the GUDID data base. § 830.300.
	All implantable devices required to be labeled with a UDI must bear a UDI as a permanent marking on the device itself. § 801.50.
Three years after publication of a final rule.	Class III devices required to be labeled with a UDI must bear a UDI as a permanent marking on the device itself if the device is (1) a device intended to be used more than once and intended to be sterilized before each use, or (2) stand-alone software regulated as a medical device. § 801.50.
	The label and package of class II medical devices must bear a UDI. § 801.20(b)(3).
	Data for class II devices that are required to be labeled with a UDI, must be submitted to the GUDID data base. § 830.300.
Five years after publication of a final rule.	Class II devices required to be labeled with a UDI must bear a UDI as a permanent marking on the device itself if the device is (1) a device intended to be used more than once and intended to be sterilized before each use, or (2) stand-alone software regulated as a medical device. § 801.50.
	The label and package of class I medical devices and devices that have not been classified into class I, class II, or class III must bear a UDI. § 801.20(b)(4), (5).
	Data for class I devices and devices that have not been classified into class I, class II, or class III that are required to be labeled with a UDI must be submitted to the GUDID data base. § 830.300.
Seven years after publication of a final rule.	Class I devices and devices that have not been classified into class I, class II, or class III required to be labeled with a UDI must a bear UDI as a permanent marking on the device itself if the device is (1) a device intended to be used more than once and intended to be sterilized before each use, or (2) stand-alone software regulated as a medical device. § 801.50.
90 days after publication of a final rule.	All other provisions go into effect, although some will have no practical effect until other provisions listed in this table go into effect.

VIII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that would have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

IX. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov.* It is only necessary to send one set of comments. 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, and will be posted to the docket at *http://www.regulations.gov.*

X. References

We have not removed any references listed in the July 10, 2012, proposed rule. We are adding new references 12 and 13 to account for the additional costs attributable to the FDASIA amendment of section 519(f) of the FD&C Act, specifically the requirement that FDA must implement the regulation with respect to devices that are implantable, life-supporting, and life-sustaining not later than 2 years after we publish a final rule.

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.*

12. List of medical devices, by product code, that FDA considers to be implantable, life-saving, and life-sustaining for purposes of section 614 of FDASIA, amending section 519(f) of the FD&C Act, November 2012.

13. Addendum to the Preliminary Regulatory Impact Analysis of the Proposed Rule to Require a Unique Device Identification System, Docket No. FDA–2011–N–0090.

List of Subjects in 21 CFR Part 801

Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.,* as amended) and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 801, as proposed to be amended in the **Federal Register** of July 10, 2012 (77 FR 40736), be further amended as follows:

PART 801—LABELING

1. The authority citation for part 801 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 360i, 360j, 371, 374.

Subpart B—[Amended]

2. Revise § 801.20(b) to read as follows:

§ 801.20 Label to bear a unique device identifier (UDI).

* * * * *

(b) *Effective dates.* The requirements of paragraph (a) of this section become effective:

(1) If the device is a class III medical device or is a device licensed under section 351 of the Public Health Service Act, as amended, 5 U.S.C. 262, [A DATE WILL BE ADDED THAT IS 1 YEAR AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE **Federal Register**];

(2) If the device is an implantable, life-supporting, or life-sustaining device, and is not a class III device or a device licensed under section 351 of the Public Health Service Act, as amended, 5 U.S.C. 262, [A DATE WILL BE ADDED THAT IS 2 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE **Federal Register**];

(3) If the device is a class II medical device not covered by paragraph (2), [A DATE WILL BE ADDED THAT IS 3 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE **Federal Register**];

(4) If the device is a class I medical device not covered by paragraph (2), [A DATE WILL BE ADDED THAT IS 5 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE **Federal Register**];

(5) If the device is not classified into class I, II, or III, [A DATE WILL BE ADDED THAT IS 5 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE **Federal Register**].

* * * * *

3. Revise § 801.50(d) to read as follows:

§ 801.50 Devices that must be directly marked with a unique device identifier.

* * * * *

(d) *Effective dates.* The requirements of this section apply to a device that is an implantable, life-supporting, or life-sustaining device [A DATE WILL BE ADDED THAT IS 2 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE **Federal Register**], and to any other device 2 years after the date that applies to the device under § 801.20(b).

* * * * *

Dated: November 14, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–28015 Filed 11–16–12; 8:45 am]

BILLING CODE 4160–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2010–0141; FRL–9752–8]

Approval and Promulgation of Air Quality Implementation Plans; Delaware; Attainment Plan for the Philadelphia-Wilmington, Pennsylvania-New Jersey-Delaware 1997 Fine Particulate Matter Nonattainment Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a State Implementation Plan (SIP) revision submitted by Delaware on April 3, 2008, as amended on April 25, 2012. The SIP revision demonstrates attainment of the 1997 annual fine particulate matter ($PM_{2.5}$) national ambient air quality standard (NAAQS) for the Philadelphia-Wilmington, Pennsylvania-New Jersey-Delaware (PA–NJ–DE) nonattainment area (Philadelphia Area). This Delaware SIP revision (herein called the ''attainment plan'') includes the Philadelphia Area's attainment demonstration and motor vehicle emission budgets (MVEBs) used for transportation conformity purposes for New Castle County in Delaware. The attainment plan also includes an analysis of reasonably available control measures (RACM) and reasonably available control technology (RACT), a base year emissions inventory, and contingency measures. The April 25, 2012 submittal is a SIP revision that replaces the MVEBs in the April 3, 2008 submittal with a budget that is based on the Motor Vehicle Emissions Simulator (MOVES) model. In a separate and concurrent process, EPA is conducting a procedure to find adequate the MVEBs for New Castle County. Furthermore, EPA has determined that a reasonable further progress (RFP) plan is not required because Delaware projected that attainment of the 1997 annual $PM_{2.5}$ NAAQS occurred in the Philadelphia Area by the attainment date of April 2010. This action is being taken in accordance with the Clean Air Act (CAA) and the Clean Air Fine Particulate Implementation Rule ($PM_{2.5}$ Implementation Rule) published on April 25, 2007.

DATES: Written comments must be received on or before December 19, 2012.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R03–OAR–2010–0141 by one of the following methods:

A. *www.regulations.gov.* Follow the on-line instructions for submitting comments.

B. *Email: mastro.donna@epa.gov.*

C. *Mail:* EPA–R03–OAR–2010–0141, Donna Mastro, Acting Associate Director, Office of Air Planning Program, Mailcode 3AP30, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R03–OAR–2010–0141. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is