Medical Device Labeling; Unique Device Identification
21 CFR 801; 21 CFR 830

OMB Control No. 0910-0485 - Revision

SUPPORTING STATEMENT – **Part A: Justification:**

1. Circumstances Making the Collection of Information Necessary

This information collection helps support implementation of statutory and regulatory requirements that govern the labeling of medical devices. Medical device labeling requirements established in section 502 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) provide, among other things, that every medical device and every device package bear a unique device identifier (UDI). Implementing regulations are found in 21 CFR part 801, subpart B (Labeling Requirements for Unique Device Identification), including provisions for exceptions from UDI requirements (21 CFR 801.30). Applicable regulations are also found in 21 CFR part 821 (Medical Device Tracking Requirements); 21 CFR part 822 (Postmarket Surveillance); 21 CFR part 814 (Premarket Approval of Medical Devices); and 21 CFR part 820 (Quality System Regulations), as well as regulations pertaining to in vitro device labeling, biological device product labeling, or any article subject to the device labeling provisions in section 502 of the FD&C Act.

For operational efficiency therefore, we are revising the information collection to include burden that may be attributable to activities associated with provisions found in 21 CFR part 830 (21 CFR 830), currently approved in OMB control no. 0910-0720, and established through rulemaking on September 24, 2013 (0910-AG31). The regulations define relevant terms, identify specific data requirements, and incorporate global standards applicable to use and discontinuation of a UDI. The regulations also provide for FDA accreditation of an issuing agency (21 CFR 830.110) and explain associated information collection activities including the establishment, maintenance, and disclosure of records. Finally, the regulations provide for administration of the Global UDI Database (GUDID) (21 CFR 830, subpart E), which specifies data that must be submitted to FDA to be made publicly available. Users of the GUDID will be able to input the device identifier portion of the UDI to query descriptive data about a specific device. The GUDID may be accessed on our website at https://www.fda.gov/medical-devices/unique-device-identification-system-udi-system/global-unique-device-identification-database-gudid. We are also revising the information collection to include labeling provisions pertaining to exceptions or alternatives to the labeling of products in the Strategic National Stockpile (SNS), provided for in agency regulations at 21 CFR 801.128 and 809.11, applicable to medical device and in vitro device products, respectively, and currently approved in control no. 0910-0614.

Accordingly. we request approval for the information collection provisions in 21 CFR part 801, subpart B, pertaining to UDI requirements and labeling exceptions applicable to the SNS, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

We use the information collection to ensure adherence to statutory and regulatory requirements. Products not in compliance with applicable statutory and regulatory labeling requirements may be subject to enforcement action by FDA.

3. Use of Improved Information Technology and Burden Reduction

The information collection is effected through electronic means. Respondents include UDI information in accordance with the applicable requirements in respective submissions to FDA and manufacturers of medical device products must ensure the disclosure of required labeling to consumers.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. Additional provisions applicable to the UDI element are found in a number of agency regulations and approved in our current inventory, including those ICRs listed here:

21 CFR part 821 (Medical Device Tracking Requirements), 0910-0442
21 CFR part 822 (Postmarket Surveillance); 0910-0822
21 CFR part 814 (Premarket Approval of Medical Devices); 0910-0231
21 CFR part 820 (Quality System Regulations), 0910-0073

Upon OMB approval of our request to include burden now accounted for in 0910-0614, we will discontinue use of that information collection.

5. Impact on Small Businesses or Other Small Entities

We do not believe the information collection imposes undue burden on small entities.

6. Consequences of Collecting the Information Less Frequently

The information collection is consistent with applicable statutory and regulatory requirements.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In the *Federal Register* of August 24, 2022, we published a notice soliciting public comment on the proposed information collection; no comments were received.

9. Explanation of Any Payment or Gift to Respondents

No remuneration is associated with the information collection.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act of 1974: In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. This ICR does not collect personally identifiable information (PII) or information of a personal nature. UDI information is a required element of product labeling. The information disclosure is used to inform users and medical professionals regarding the safety and efficacy of the device(s). Recordkeeping is performed to comply with the requirement to maintain the product labeling online for users and medical professionals. Because neither FDA nor any party acting on behalf of the agency collects PII, the ICR is not subject to the Privacy Act of 1974 and the requirements of the Privacy Act, such as displaying a Privacy Act Statement on a collection form do not apply.

The Freedom of Information Act: Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Recordkeeping Burden[1]

Part 801 – Labeling Requirements	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
§ 830; requirements for a unique device identifier	6,199	51	316,149	1	316,149
801.128 and 809.11; exceptions or alternatives to labeling requirements for products held by the SNS	2	1	2	24	48
TOTAL	0		0		0

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

12b. Annualized Cost Burden Estimate

To calculate estimated annual costs to industry we assume wage rates commensurate with that of the "*Compliance Officer*" category established by the Bureau of Labor Statistics, BLS Compliance Officer:

Occupation code	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
13-1041 Compliance Officer	316,197	$36.45	$11,525,380.65

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no other annual costs to the respondents of the information collection.

14. Annualized Cost to the Federal Government

Our currently approved cost estimate of $2,633,260 FDA for administering the information collection.

15. Explanation for Program Changes or Adjustments

We have adjusted our estimate to reflect an increase of 316,151 responses and 316,197 hours to account for program changes resulting from the implementation of two previous agency rulemakings. Although we discussed provisions established from 2007 rulemaking pertaining to UDI requirements in our 60- and 30-day *Federal Register* notices, only upon our reevaluation of the inventory and submission to OMB are we requesting revision for SNS product labeling provisions established under 801.128 and 809.11 from rulemaking in 2007 and currently approved in 0910-0614. We inadvertently omitted accounting for the incorporation of these labeling requirements into our subsequent requests for extension of labeling provisions.

16. Publication and Project Time Schedule

Information collection supports rulemaking included on FDA's Regulatory Agenda.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Display of the OMB expiration date as required by 5 CFR 1320.5 is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.