TABLE 6—CLASS II DEVICES AND UNCLASSIFIED DEVICES PROPOSED EXEMPT FROM 510(k) REQUIREMENT—Continued

Device description	Device class	Product code	Section in 21 CFR
Oxygenator, Long Term Support Greater Than 6 Hours	II	FXY	878.4040
Transmitters And Receivers, Electrocardiograph, Telephone	II	ONT	878.4040
Extracorporeal System For Long-Term Respiratory/Cardiopulmonary Failure	II	OMC	882.1400
Implanted Subcutaneous Securement Catheter	II	MOS	892.1000
Subcutaneous Implanted Apheresis Port	II	QHY	892.1650

C. Impact of Exemptions on Patient Access to Medical Devices

With this Notice, the Department is immediately exempting 7 devices from the premarket notification requirement, and proposes to exempt an additional 84 devices from the requirement after public comment is closed. As noted above in Part I.A, estimates on the cost of preparing a 510(k) submission range from $100,000 to $4 million. The exemptions provided for and proposed under this Notice for these 91 device classes could eliminate anywhere from $9.1 to $364 million in startup costs if there were one new entrant into each device market. Savings could further accrue based on each new market entrant. Instead of being costs passed along to patients and taxpayers, these savings could be invested in other areas such as research and development and manufacturing.

At the same time, should these waivers go into effect as proposed, patients stand to gain more immediate access to new products that would otherwise be required to obtain a 510(k) clearance prior to marketing.

The exemptions provided for in this Notice also conserve FDA's scarce review resources. The COVID–19 PHE stretched FDA's review capacity. Under this Notice, FDA's review resources can be redeployed to review other innovative technology, to include devices designed to mitigate the impact of COVID–19.

IV. Request for Information, Data, and Further Study

HHS' review in this Notice warrants expansion and further study. FDA's medical device Product Code database contains 6,651 unique codes (to include those discussed in this Notice). Of those unique codes, 157 are for class I devices that require 510(k) clearance, and 2,662 are for class II devices that require 510(k) clearance. Applying the $100,000 to $4 million in estimated costs for 510(k) preparation and submission to these 2,819 devices yields approximately $281.9 million to $11.276 billion in startup costs, assuming one new market entrant in each of the 2,819 device classes. Further, again assuming a 90-day review period and one new device entrant in each of the 2,819 device classes that require 510(k) notification, FDA's current approach creates 253,710 review days or 695.1 review years between Americans and new devices. The question of whether the 510(k) notice is justified in view of safety and efficacy concerns merits comprehensive analysis for the benefit of Americans. The Department seeks public comment, research, and analysis on whether other devices should be exempt from the premarket notification requirement.

At a more detailed level, the Department observed internal inconsistencies in FDA's regulation of some device classes that merit discussion. Manual stethoscopes are exempt from the premarket notification requirement. 21 CFR 870.1875(a)(2). Electronic stethoscopes are also exempt, but only if the device ''is a lung sound monitor.'' 21 CFR 870.1875(b)(2). Similarly, FDA exempts ''clinical mercury thermometer . . . device[s] used to measure oral, rectal, or axillary (armpit) body temperature using the thermal expansion of mercury'' from the 510(k) premarket notification requirement. 21 CFR 880.2920. By contrast, clinical electronic thermometers which never enter into any body orifice require 510(k) premarket notification. 21 CFR 880.2910. These apparent inconsistencies merit scientific scrutiny. To that end, the Department seeks public comment as to whether other inconsistencies in the medical device regulatory framework exist.

Dated: January 8, 2021.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–00787 Filed 1–14–21; 8:45 am]

BILLING CODE 4150–26–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1657]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Survey of Drug Product Manufacturing, Processing, and Packing Facilities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by February 16, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comment'' or by using the search function. The title of this information collection is ''Survey of Drug Product Manufacturing, Processing, and Packing Facilities.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Survey of Drug Product Manufacturing, Processing, and Packing Facilities—21 CFR parts 210 and 211

OMB Control Number 0910–NEW

FDA has the responsibility to regulate the safety, as well as the efficacy and quality, of drugs in the United States. Under the Food and Drug Administration Safety and Innovation Act, enacted in 2012, the term current good manufacturing practice (CGMP) includes the implementation of oversight and controls over the manufacturing, processing, and packing of drugs to ensure quality, including managing the risk of, and establishing the safety of, raw materials used in the manufacture of drugs. The safety and availability of drugs can be affected by raw material suppliers, the material supply chain, and the facility's controls over raw material quality. Risk management enables manufacturers to make proper choices and ensure the continued suitability of these materials and supply chains. The Agency needs to better understand how manufacturers, processors, and packers of drug products approach managing risks related to components, containers, and closures as well as the supply and distribution chains between the producers of raw materials and drug product manufacturers, processors, and packers. Such information will allow FDA to examine the potential economic impact of changes to regulations that govern the manufacturing, processing, and packing of drugs.

In the **Federal Register** of September 18, 2020 (85 FR 58370), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four collection of information topics solicited and therefore will not be discussed in this document.

This is a one-time information collection, the primary purpose of which is to collect industry-wide data on how facilities that manufacture, process, and pack drug products for use in humans and/or animals ensure the quality of their operations, including their current risk management approaches and practices for ensuring the quality and suitability of the drug components, containers, and closures that they use. FDA intends to use this information to inform its economic analyses of potential updates to CGMPs for human and animal drug product manufacturing, processing, and packing facilities under 21 CFR parts 210 and 211. Survey respondents will be contacted by email or, if necessary, by regular mail. Respondents will be able to take the survey online or, if requested, they can return a hard copy by mail. FDA estimates the maximum burden of this collection of information as follows:

TABLE 1.—ESTIMATED BURDEN HOURS FOR ONE-TIME DATA COLLECTION[1]

Type of respondent/facility	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Group 1: Facilities in United States engaged in drug manufacturing (in addition to other possible activities).	394	1	394	1.1	433
Group 2: Facilities in United States *not* engaged in manufacturing but engaged in other forms of drug processing or packing (e.g., labeling, repacking, etc.).	333	1	333	0.75 (45 minutes)	250
Group 3: Facilities outside United States engaged in drug manufacturing (in addition to other possible activities).	407	1	407	2.20	895
Group 4: Facilities outside United States *not* engaged in manufacturing but engaged in other forms of drug processing or packing (e.g., labeling, repacking, etc.).	261	1	261	1.5	392
Total	1,395		1,395		1,970

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

Burden hours are based on pretests of the survey and interviews with industry representatives and reflect the time required by each type of respondent to read the survey invitation and instructions and complete the survey questions. The total estimated one-time burden hours are 1,970.

Dated: January 11, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–00838 Filed 1–14–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Faculty Loan Repayment Program; OMB No. 0915–0150—Revision

AGENCY: Health Resources and Services Administration, (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30 day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than February 16, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa