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: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Export of Medical Devices; Foreign Letters of Approval

OMB Control Number 0910–0264—Extension

Section 801(e)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381(e)(2)) provides for the exportation of an unapproved device under certain circumstances if the exportation is not contrary to the public health and safety and it has the approval of the foreign country to which it is intended for export. Requesters communicate (either directly or through a business associate in the foreign country) with a representative of the foreign government to which they seek exportation, and written authorization must be obtained from the appropriate office within the foreign government approving the importation of the medical device. An alternative to obtaining written authorization from the foreign government is to accept a notarized certification from a responsible company official in the United States that the product is not in conflict with the foreign country's laws. This certification must include a statement acknowledging that the responsible company official making the certification is subject to the provisions of 18 U.S.C. 1001. This statutory provision makes it a criminal offense to knowingly and willingly make a false or fraudulent statement, or make or use a false document, in any manner within the jurisdiction of a department or Agency of the United States. The respondents to this collection of information are companies that seek to export medical devices. FDA's estimate of the reporting burden is based on the experience of FDA's medical device program personnel.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/FD&C Act section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs
Foreign letter of approval—801(e)(2)	33	1	33	3	99	$8,250

[1] There are no capital costs associated with this collection of information.

We have adjusted our burden estimate by decreasing the number of respondents by 5, which has resulted in a corresponding decrease of 15 hours to the currently approved hour burden and $1,250 to the total operating and maintenance costs. This adjustment is based on a decrease in the number of submissions we received over the last few years.

Dated: March 5, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–04283 Filed 3–8–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0299]

Nonprescription Naloxone Labeling Resources; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a model Drug Facts label (DFL) for nonprescription naloxone. Naloxone is a drug used to treat opioid overdose. FDA is making the DFL and supporting data available for use by applicants seeking approval of naloxone drug products that can be obtained without a prescription.

FOR FURTHER INFORMATION CONTACT: Sherry Stewart, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5494, Silver Spring, MD 20993–0002, 301–796–9618.

SUPPLEMENTARY INFORMATION:

I. Background

The increasing incidence of misuse and abuse of illicit and prescription opioids and the associated risks of addiction, overdose, and death have resulted in a public health crisis in the United States. Opioid overdose is characterized by life-threatening respiratory and central nervous system depression that, if not immediately

treated, may lead to significant morbidity and mortality. When administered quickly after an opioid overdose, naloxone, an opioid antagonist, can save lives. Naloxone is currently approved as a prescription drug, but it is not approved for nonprescription use. As part of a wide governmental effort to address the national crisis of opioid overdose deaths, the Agency has identified broader availability of naloxone, including potential nonprescription availability, as one means to help reduce overdose deaths.

To support approval of a drug for nonprescription use, the sponsor of the drug product typically (among other things) conducts one or more consumer behavior studies to demonstrate that consumers would be able to use the drug product safely and effectively in the nonprescription setting without the supervision of a healthcare professional. Some stakeholders have identified the need to perform these studies as a barrier to development of a nonprescription naloxone drug product. To help address this concern, FDA developed a model DFL for a potential nonprescription naloxone drug product. The model DFL is intended to contain adequate information (except for individual device-specific information, such as how to use a particular injector or spray device, which would be added by the product sponsor) that a consumer would need to administer naloxone safely and effectively for its intended use in the nonprescription setting. Consumer comprehension of the model DFL has been iteratively tested by an independent research contractor in a prespecified research design involving over 700 participants across a wide range of potential nonprescription naloxone users. These participants included people who use heroin, people who use prescription opioids, family and friends of people who use opioids, adolescents, and members of the general public.

After completion of the label comprehension study, an FDA review team that was not involved in the design or conduct of the study reviewed the study report and determined that the comprehension results are adequate. FDA has determined that the model DFL can be made publicly available so that sponsors who wish to pursue development of a nonprescription naloxone product can use the model DFL in their development program. A sponsor would need to add its device-specific information to the model DFL and retest that information to demonstrate that consumers understand the information within the context of the overall DFL. The model DFL comes in two versions (one for use with a nasal spray and one for use with an injector), but the device-specific instructions in each version are placeholders that have not been tested for comprehension or human factors performance, and sponsors will need to replace these placeholders with their own device-specific information and retest it appropriately.

FDA strongly encourages sponsors of potential nonprescription naloxone drug products to request a meeting to discuss their development program with the Division of Nonprescription Drug Products. For information on sponsor meetings with FDA, sponsors can refer to the draft guidance for industry ''Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products'' at *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm590547.pdf.*

II. Electronic Access

Persons with access to the internet may obtain the model DFLs at *https://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM629320.pdf* and *https://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM629321.pdf.*

Dated: March 6, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–04357 Filed 3–8–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

''Low-Income Levels'' Used for Various Health Professions and Nursing Programs Authorized in the Public Health Service Act

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

ACTION: Notice.

SUMMARY: HRSA is updating income levels used to identify a ''low-income family'' for the purpose of determining eligibility for programs that provide health professions and nursing training to individuals from disadvantaged backgrounds. These various programs are authorized in Titles III, VII, and VIII of the Public Health Service Act.

SUPPLEMENTARY INFORMATION: HHS periodically publishes in the **Federal Register** low-income levels to be used by institutions receiving grants and cooperative agreements to determine eligibility for programs providing training for (1) disadvantaged individuals, (2) individuals from disadvantaged backgrounds, or (3) individuals from low-income families.

Many health professions and nursing grant and cooperative agreement awardees use the low-income levels to determine whether potential program participants are from an economically disadvantaged background and would be eligible to participate in the program, as well as to determine the amount of funding the individual receives. Awards are generally made to accredited schools of allopathic medicine, osteopathic medicine, public health, dentistry, veterinary medicine, optometry, pharmacy, allied health, podiatric medicine, nursing, and chiropractic; public or private nonprofit schools, which offer graduate programs in behavioral health and mental health practice; and other public or private nonprofit health or education entities to assist the disadvantaged to enter and graduate from health professions and nursing schools. Some programs provide for the repayment of health professions or nursing education loans for disadvantaged students.

A ''low-income family/household'' for programs included in Titles III, VII, and VIII of the Public Health Service Act is defined as having an annual income that does not exceed 200 percent of the Department's poverty guidelines. A family is a group of two or more individuals related by birth, marriage, or adoption who live together.

Most HRSA programs use the income of a student's parents to compute low-income status. However, a ''household'' may potentially be only one person. Other HRSA programs, depending upon the legislative intent of the program, the programmatic purpose related to income level, as well as the age and circumstances of the participant, will apply these low-income standards to the individual student to determine eligibility, as long as he or she is not listed as a dependent on the tax form of his or her parent(s). Each program announces the rationale and choice of methodology for determining low-income levels in program guidance.

Low-income levels are adjusted annually based on HHS' poverty guidelines. HHS' poverty guidelines are based on poverty thresholds published by the U.S. Census Bureau, adjusted annually for changes in the Consumer Price Index. The income figures below