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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.

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