when a dose is taken and how much is taken, and limit further access until it is time for the next dose. Additionally, many of these drug-device combinations electronically encrypt and capture the accumulated adherence data, which can be downloaded directly from the device or wirelessly transmitted to the prescriber. These technologies have not only been used in clinical management and monitoring of protocol compliance in clinical trials, but have also been applied to combat the problem of prescription opioid misuse and abuse.

Other potentially relevant technologies include ''track and trace'' capabilities, radio-frequency identification-based systems, microchips embedded within tablets, and in-home medication deactivation and/or disposal systems.

FDA is interested in further exploring the role of existing and innovative designs for drug product packaging, storage, and/or disposal in mitigating opioid misuse, abuse, and addiction. For example, many of the features of medication adherence monitoring technologies could be used or adapted to help prevent serious complications (e.g., overdose, addiction) by supporting proper dosage and administration, and could also help prescribers monitor for signs of abuse or medication sharing by facilitating effective patient management and followup. Additionally, medication packaging and/or storage designs that limit access could help prevent use of the medication by someone for whom it was not prescribed, thereby, preventing accidental exposure (e.g., by a child or other household contact) or theft. Finally, medication packaging, storage, and/or disposal designs could be applied or adapted to help ensure safe disposal, including chemical deactivation, of any unused or residual medication.

II. Establishment of a Docket

FDA is announcing the establishment of a public docket to provide an opportunity for interested persons to share information, research, and ideas on how drug product packaging, storage, and/or disposal systems could be designed or adapted to address problems associated with prescription opioid abuse and misuse. These comments will help the Agency explore whether existing or innovative designs can be applied or adapted to prevent or deter misuse and abuse, while ensuring that patients in pain have appropriate access to opioid analgesics.

III. Suggestions for Those Submitting Comments in Response to This Notice

Proposed packaging, storage, and/or disposal designs should be feasible to implement, and should not impair access for patients who have legitimate prescriptions. Comments about specific system or technology designs should include a description of the following: (1) Design features and functionality; (2) results of any formative or summative human factors assessments conducted; (3) applications to date, including information on the effectiveness and acceptability of those applications (with literature references or other documentation); (4) recommendations for how the system/technology design could be applied or adapted (either alone and/or in combination with other systems/technologies) to help prevent or deter misuse and abuse, and any limitations of that application; (5) specific problems that could be addressed (e.g., serious complications such as addiction or overdose due to improper dosage and/or administration, improper disposal, accidental use by someone for whom the medication was not prescribed); and (6) to the extent possible, considerations for implementation into routine dispensing and clinical use (e.g., how the solution would impact the workflow in a retail pharmacy).

To help FDA prioritize among proposed approaches, the Agency is also interested in receiving feedback about methods that could be used to assess a system or technology's potential abuse-deterrent characteristics and real-world impact (e.g., actual ability to prevent or deter misuse and abuse, effect on access for appropriate patients, patient confidentiality, burden on the healthcare system, feasibility of implementation, whether the design could create unintended medication errors). Finally, FDA is interested in receiving feedback on methods for encouraging further research and development in this area, and, if promising technologies are identified, incentivizing the pharmaceutical industry (e.g. via patent extensions) to adopt such technologies.

IV. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). 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.* The Agency will carefully consider all comments submitted. FDA generally will not respond directly to the person or organization submitting the comment.

V. References

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. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Centers for Disease Control and Prevention. ''Opioids drive continued increase in drug overdose deaths'' [Press Release] (2013). *http://www.cdc.gov/media/releases/2013/p0220_drug_overdose_deaths.html.*

2. SAMHSA, Center for Behavioral Health Statistics and Quality. Treatment Episode Data Set (TEDS): 2001–2011. *National Admissions to Substance Abuse Treatment Services.* BHSIS Series S–65, HHS Publication No. (SMA) 13–4772. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

3. SAMHSA, Center for Behavioral Health Statistics and Quality, ''Drug Abuse Warning Network,'' 2011. *http://samhsa.gov/data/dawn/nations/Nation_2011_AllMA.xls.*

4. Substance Abuse and Mental Health Services Administration, *Results from the 2012 National Survey on Drug Use and Health,* detailed table 1.1A, NSDUH Series H–46, HHS Publication No. (SMA) 13–4795. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

Dated: April 2, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–07909 Filed 4–8–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2006–P–0207]

Draft Guidance for Industry: Proper Labeling of Honey and Honey Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled ''Guidance for Industry: Proper Labeling

of Honey and Honey Products.'' FDA developed this draft guidance to advise firms on the proper labeling of honey and honey products to help ensure that honey and honey products are not adulterated or misbranded.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by June 9, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Nutrition, Labeling, and Dietary Supplements (HFS–820), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: April Kates, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2371.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Proper Labeling of Honey and Honey Products'' dated February 2014. On March 8, 2006, the American Beekeeping Federation and several other honey-related associations submitted a citizen petition requesting that FDA adopt a U.S. standard of identity for honey based on the 2001 Revised Codex Alimentarius Commission's Standard for Honey. The petitioners asserted that a U.S. standard of identity for honey would achieve the following goals: (1) Clarify what the term ''honey'' means with respect to the food's composition and therefore promote honesty and fair dealing in the interest of consumers; (2) combat economic adulteration of honey by aiding enforcement and industry compliance; and (3) promote honesty and fair dealing within the food trade in general, where pure honey is used as an ingredient in other food. In a letter dated October 5, 2011, we denied the petition because the petition did not provide reasonable grounds for FDA to adopt the Codex standard for honey. We also concluded that the petitioners' goals can be achieved by FDA's existing authorities and that a standard of identity for honey would not promote honesty and fair dealing in the interest of consumers.

To address the labeling issues relevant to the petition, we developed this draft guidance to advise the regulated food industry on the proper labeling of honey and honey products to help ensure that honey and honey products are not adulterated or misbranded under sections 402 and 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342 and 343, respectively).

We are issuing this draft guidance document consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on the labeling of honey and honey products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 101.4, 101.22, and 102 have been approved under OMB control number 0910–0381.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). 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*.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance document at *http://www.fda.gov/FoodGuidances* or *http://www.regulations.gov*.

Dated: April 4, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–07925 Filed 4–8–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0310]

Draft Guidance for Industry on Immunogenicity-Related Considerations for the Approval of Low Molecular Weight Heparin for New Drug Applications and Abbreviated New Drug Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Immunogenicity-Related Considerations for the Approval of Low Molecular Weight Heparin for NDAs and ANDAs.'' This guidance discusses how applicants for low molecular weight heparin (LMWH) products should provide information on impurities and the potential impact on immunogenicity.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by June 9, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Daniela Verthelyi, Center for Drug Evaluation and Research (HFD–122), Food and Drug Administration, 9000 Rockville Pike, N29A, Rm. 3B19, Bethesda, MD 20892, 301–827–1702.