the information collection requirements relating to the Small Business Innovation Research Program (SBIR)—Phase II.

DATES: Submit written or electronic comments on the collection of information by October 5, 2015.

ADDRESSES: Submit electronic comments on the collection of information to: *Brian.Bard@acl.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Brian Bard at 202–254–7345 or *Brian.Bard@acl.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 request 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, ACL/NIDILRR is publishing notice of the proposed collection of information set forth in this document. With respect to the following collection of information, ACL/NIDILRR invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of ACL/NIDILRR's functions, including whether the information will have practical utility; (2) the accuracy of ACL/NIDILRR'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. ACL/NIDILRR proposes to use this set of data collection tools to be used as a grant application package for the information used to apply for new grants under the SBIR program (Phase II).

Public Law 106–554, the ''Small Business Reauthorization Act of 2000, H.R. 5567'' (the ''Act'') was enacted on December 21, 2000. The Act requires certain agencies, including the Department of Health and Human Services (HHS) to establish a Small Business Innovation Research (SBIR) program by reserving a statutory percentage of their extramural research and development budgets to be awarded to small business concerns for research or research and development (R/R&D) through a uniform, highly competitive, three-phase process each fiscal year. The Act further requires the Small Business Administration (SBA) to issue policy directives for the general conduct of the SBIR programs within the Federal Government. The purpose of this program is to stimulate technological Innovation in the private sector, strengthen the role of small business in meeting Federal research and research and development needs, increase the commercial application of Department of Education (ED) supported research results, and improve the return on investment from Federally-funded research for economic and social benefits to the Nation.

Awards are made on the basis of competitively reviewed applications. The Department is requesting approval of this grant application package for the information used to apply for new grants under the Small Business Innovation Research (SBIR) Phase II program. Phase I is intended to determine, insofar as possible, the scientific or technical merit and feasibility of ideas. Phase II is intended to expand on the results of and to further pursue the development of a Phase I project. Phase II is the principal research and research and development effort. It requires a more comprehensive application, outlining the effort in detail including the commercial potential. Phase II applications must be Phase I grantees with findings that appear sufficiently promising as a result of Phase I. Applications are evaluated based on published criteria by panels of experts.

ACL/NIDILRR estimates the burden of this collection of information as 240 hours for project staff, 320 for reviewers, and 1,080 hours for individuals. Total burden is 1,640 hours per year.

Dated: July 31, 2015.

Kathy Greenlee,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2015–19237 Filed 8–4–15; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1009]

Use of Nanomaterials in Food for Animals; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of guidance for industry #220 entitled ''Use of Nanomaterials in Food for Animals.'' The guidance describes FDA's current thinking regarding the use of nanomaterials or the application of nanotechnology in food for animals. It is intended to assist industry and other stakeholders in identifying potential issues related to the safety or regulatory status of food for animals containing nanomaterials or otherwise involving the application of nanotechnology.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the 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: Dragan Momcilovic, Center for Veterinary Medicine (HFV–226), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–453–6856, *dragan.momcilovic@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 27, 2014 (79 FR 36530), FDA published the notice of availability for a draft guidance #220 entitled ''Use of Nanomaterials in Food for Animals'' giving interested persons until September 10, 2014, to comment on the draft guidance. FDA received several comments on the draft guidance and those comments were

considered as the guidance was finalized. The guidance announced in this notice finalizes the draft guidance dated June 2014.

II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on the use of nanomaterials in food for animals. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This 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 571.1 and 21 CFR 571.6 have been approved under 0910–0546.

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*.

V. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *http://www.regulations.gov*.

Dated: July 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–19179 Filed 8–4–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1473]

Over-the-Counter Pediatric Oral Liquid Drug Products Containing Acetaminophen; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a guidance for industry entitled ''Over-the-Counter Pediatric Oral Liquid Drug Products Containing Acetaminophen.'' The guidance is intended to help drug manufacturers, packagers, and labelers minimize the risk to consumers of acetaminophen-related liver damage associated with the use of nonprescription, also known as over-the-counter or OTC, pediatric oral liquid acetaminophen drug products. This guidance provides recommendations regarding acetaminophen concentration, container labels, carton labeling, and packaging of such products, as well as for any associated delivery devices. FDA's recommendations are designed to encourage safer use of these products by minimizing the potential for acetaminophen overdosing due to medication errors or accidental ingestion.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, 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 guidance document.

Submit electronic comments on the 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: Alice Tu, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4325, Silver Spring, MD 20993–0002, 301–796–7586.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Over-the-Counter Pediatric Oral Liquid Drug Products Containing Acetaminophen.'' Acetaminophen is marketed in many OTC drug products as a pain reliever and fever reducer. Most OTC acetaminophen products are marketed under FDA's ongoing rulemaking to establish a final monograph for OTC internal analgesic, antipyretic, and antirheumatic (IAAA) drug products. These products must conform to the conditions described in FDA's Tentative Final Monograph for Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter (OTC) Human Use (the IAAA TFM) [1] and FDA's general regulations for OTC drug marketing (21 CFR 330.1) and labeling (21 CFR 330.10 and part 201). They also must be labeled with acetaminophen-related warnings and other information as specified in 21 CFR 201.326. However, OTC pediatric oral liquid drug products containing acetaminophen have been associated with overdoses due to medication errors that resulted in serious adverse events, including severe liver damage and death. In particular, there have been reports of overdose attributed to confusion between concentrated acetaminophen drops (80 milligrams (mg)/0.8 milliliters (mL) and 80 mg/mL) and acetaminophen oral liquid (160 mg/5 mL).

This guidance document is part of FDA's ongoing initiative to reduce the risk of acetaminophen-related liver injury associated with all OTC and prescription acetaminophen-containing products. As part of that initiative, in June 2009, three FDA committees, the Drug Safety and Risk Management Advisory Committee, the Nonprescription Drugs Advisory Committee, and the Anesthetic and Life Support Drugs Advisory Committee, met jointly to consider a range of risk reduction measures. Among other measures, these Advisory Committees recommended moving to a single, standardized acetaminophen concentration for OTC pediatric oral liquid drug products because the availability of multiple concentrations causes confusion and errors among both consumers and health care

[1] ''Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Tentative Final Monograph,'' 53 FR 46204 (November 16, 1988). Available at *http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Over-the-CounterOTCDrugs/StatusofOTCRulemakings/UCM078460.pdf.*