''current,'' the transitional pass-through payment began on the first date the hospital OPPS was implemented (before enactment of Benefits Improvement and Protections Act (BIPA) (Pub. L. 106–554), on December 21, 2000). Transitional pass-through payments are also required for certain ''new'' drugs, devices and biological agents that were not being paid for as a hospital outpatient department (OPD) service as of December 31, 1996, and whose cost is ''not insignificant'' in relation to the outpatient perspective payment system (OPPS) payment for the procedures or services associated with the new drug, device, or biological. Under the statute, transitional pass-through payments can be made for at least 2 years but not more than 3 years. We have qualified thousands for transitional pass-through payments through our application process. However, to keep pace with emerging new technologies and make them accessible to Medicare beneficiaries in a timely manner as the law intended, it is necessary that we continue to collect appropriate information from interested parties such as hospitals and pharmaceutical companies that bring to our attention specific new drugs, biologicals and radiopharmaceuticals to be evaluated for transitional pass-through status. *Form Number:* CMS–10008 (OMB control number: 0938–0802); *Frequency:* Yearly; *Affected Public:* Private sector (Business or other for-profit institutions); *Number of Respondents:* 30; *Total Annual Responses:* 30; *Total Annual Hours:* 480. (For policy questions regarding this collection contact Raymond Bulls at 410–786–7267).

4. *Type of Information Collection Request:* New collection (Request for new OMB control number); *Title of Information Collection:* Medicare Enrollment Application for Physician and Non-Physician Practitioners; *Use:* The application is used by Medicare contractors to collect data to ensure that the applicant has the necessary credentials to provide the health care services for which they intend to bill Medicare, including information that allows the Medicare contractor to correctly price, process and pay the applicant's claims. This application collects information to ensure that only legitimate physicians, non-physician practitioners, and other eligible professionals are enrolled in the Medicare program. It is meant to be the first line defense to protect our beneficiaries from illegitimate providers and to protect the Medicare Trust Fund against fraud. It also gathers information that allows Medicare contractors to ensure that the provider/supplier is not sanctioned from the Medicare and/or Medicaid program(s), or debarred, suspended or excluded from any other Federal agency or program. *Form Number:* CMS–855I (OMB control number: 0938—NEW); *Frequency:* On Occasion; *Affected Public:* State, Local, or Tribal Governments, Private Sector (not-for-profit institutions); *Number of Respondents:* 513,872; *Total Annual Responses:* 1,370,078; *Total Annual Hours:* 1,000,167. (For policy questions regarding this collection contact Kimberly McPhillips at 410–786–5374).

5. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Outcome and Assessment Information Set (OASIS) OASIS–C2/ICD–10; *Use:* This request is for OMB approval to modify the Outcome and Assessment Information Set (OASIS) that home health agencies (HHAs) are required to collect in order to participate in the Medicare program. The current version of the OASIS, OASIS–C2 (0938–1279) data item set was approved by the Office of Management and Budget (OMB) on December 9, 2016 and implemented on January 1, 2017. We are seeking OMB approval for the proposed revised OASIS item set, referred to hereafter as OASIS–D, scheduled for implementation on January 1, 2019. The OASIS D is being modified to: Include changes pursuant to the Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act); accommodate data element removals to reduce burden; and improve formatting throughout the document. *Form Number:* CMS–10545 (OMB control number: 0938–1279); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other for-profit and Not-for-profit institutions); *Number of Respondents:* 12,149; *Total Annual Responses:* 18,161,942; *Total Annual Hours:* 9,943,141. (For policy questions regarding this collection contact Joan Proctor at 410–786–0949.)

Dated: March 7, 2018.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2018–04893 Filed 3–9–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–0626]

Proprietary Names for New Animal Drugs; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry #240 entitled ''Proprietary Names for New Animal Drugs.'' This draft guidance provides recommendations to help new animal drug sponsors develop proprietary names for new animal drugs that do not contribute to medication errors, negatively impact safe use of the drug, or misbrand the drug. This draft guidance proposes a framework for evaluating proposed proprietary names before submitting them for review by the Center for Veterinary Medicine (CVM or we). It also explains how new animal drug sponsors can request that CVM evaluate a proposed proprietary name.

DATES: Submit either electronic or written comments on the draft guidance by May 11, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you

do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–D–0626 for ''Proprietary Names for New Animal Drugs.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

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, 7500 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Tom Modric, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5853, *tomislav.modric@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry #240 entitled ''Proprietary Names for New Animal Drugs.'' CVM evaluates proprietary names as a part of the new animal drug approval process. Selecting a proprietary name is a critical element in the design and development of drug product labeling because end users may rely, in part, on the proprietary name to identify which product, among thousands of available products, is intended for a given animal.

II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Proprietary Names for New Animal Drugs.'' 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. This is not a significant regulatory action subject to Executive Order 12866.

III. 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 part 514 have been approved under OMB control numbers 0910–0032 and 0910–0699; 21 CFR part 511 have been approved under OMB control number 0910–0117.

IV. Electronic Access

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

Dated: March 6, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–04885 Filed 3–9–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Service Administration

Bright Futures Periodicity Schedule Updates

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

ACTION: Notice.

SUMMARY: Effective December 21, 2017, HRSA updated the HRSA-supported guidelines for infants, children, and adolescents for purposes of health insurance coverage for preventive services, as set out in the Bright Futures Periodicity Schedule. This notice serves as an announcement of the decision to update these guidelines as listed below. Please see *https://mchb.hrsa.gov/maternal-child-health-topics/child-health/bright-futures.html* for additional information.

FOR FURTHER INFORMATION CONTACT: Bethany D. Miller, LCSW–C, M.Ed., HRSA/Maternal and Child Health Bureau by calling (301) 495–5156 or emailing *BMiller@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The Bright Futures program has been funded by HRSA since 1990. A primary focus of this program is for the funding recipient to maintain and update the *Bright Futures Guidelines for Health Supervision of Infants, Children and Adolescents,* a set of materials and tools that provide theory-based and evidence-driven guidance for all preventive care screenings and well-child visits. One component of these tools is the Bright Futures Periodicity Schedule, a chart