

*Estimated Total Annual Burden Hours: 6,160.*

**Comments:** The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

**Authority:** 42 U.S.C. 1397 through 1397e.

**John M. Sweet Jr.,**

*ACF/OPRE Certifying Officer.*

[FR Doc. 2020-20447 Filed 9-15-20; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2020-N-0026]

#### **Issuance of Priority Review Voucher; Rare Pediatric Disease Product**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that KOSELUGO (selumetinib, AZD6244), manufactured by AstraZeneca Pharmaceuticals, LP, meets the criteria for a priority review voucher.

**FOR FURTHER INFORMATION CONTACT:** Althea Cuff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-4061, Fax: 301-796-9856, email: [althea.cuff@fda.hhs.gov](mailto:althea.cuff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined that KOSELUGO (selumetinib, AZD6244), manufactured by AstraZeneca Pharmaceuticals, LP, meets the criteria for a priority review voucher.

KOSELUGO (selumetinib, AZD6244) is indicated for the treatment of pediatric patients 2 years of age and older with neurofibromatosis type 1 who have symptomatic, inoperable plexiform neurofibromas.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to <http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseases/Conditions/RarePediatricDiseasePriorityVoucherProgram/default.htm>. For further information about KOSELUGO (selumetinib, AZD6244), go to the "Drugs@FDA" website at <http://www.accessdata.fda.gov/scripts/cder/daf/>.

Dated: September 10, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2020-D-1621]

#### **Geriatric Information in Human Prescription Drug and Biological Product Labeling; Draft Guidance for Industry; Availability**

**AGENCY:** Food and Drug Administration, Health and Human Services (HHS).

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Geriatric Information in Human Prescription Drug and Biological Product Labeling." This draft guidance is intended to assist applicants of human prescription drug and biological products in determining the appropriate placement and content of geriatric information in labeling. The goal of this draft guidance is to provide

recommendations to help ensure that appropriate information on the use of prescription drugs and biological products in geriatric patients is consistently placed in the proper sections and subsections within labeling so that the information is clear and accessible to health care practitioners and includes content that guides the safe and effective use in geriatric patients. This draft guidance provides additional examples of geriatric use statements in labeling and examples of when the labeling regulations authorize FDA to permit applicants to omit or revise specific information otherwise required in the *Geriatric Use* subsection. We are withdrawing the guidance for industry entitled "Content and Format for Geriatric Labeling" (October 2001) and replacing it with this draft guidance.

**DATES:** Submit either electronic or written comments on the draft guidance by November 16, 2020 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