

- Collecting program official, caseworker, and resident beneficiary level data from the Affordable Housing and Supportive Services Demonstration.
 - Conducting interviews with program officials and caseworkers that administer the supportive services to residents living in affordable housing units to better understand their program implementation efforts and responses to resident needs.
 - Conducting focus groups with beneficiary residents to understand their needs and experiences with the
- supportive services offered in their affordable housing residence.

 - Administering a self-sufficiency matrix to beneficiary residents to assess any change or improvement in beneficiary resident reporting of overall self-sufficiency and wellbeing, which is measured using several indicators, with the receipt of additional supportive services in the affordable housing setting.

Respondents: There will be three types of respondents to the proposed instruments. First, the direct
- beneficiaries living in the residential housing communities will respond to instruments 1, 2, and 3. Second, the program directors/administrative staff will respond to instruments 4, 5, 6, and 7. Finally, the caseworkers providing direct support to beneficiaries will respond to instrument 8. Caseworkers may also be asked to support the implementation and administration of instruments 1, 2, and 3.

ANNUAL BURDEN ESTIMATES				
Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total/annual burden hours
1—Self-Sufficiency Matrix	560	2	1.5	1,680
2—Service Receipt Questionnaire	560	2	.25	280
3—Resident Focus Group	25	1	1.5	37.5
4—Quarterly PPR Questions	9	4	2	72
5—Semi-Annual Report MANDATORY	9	2	3	54
6—Semi-Annual Report OPTIONAL	3	2	1	6
7—Interviews of Program Directors	18	1	1.5	27
8—Interviews of Caseworkers	18	1	1	18
Estimated Total Annual Burden Hours				2,174.5

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. Comments will be considered and any necessary updates to materials made prior to, and responses provided in, the submission to OMB that will follow this public comment period.

Authority: Sec. 1110, Social Security Act, 42 U.S.C. 1310.

Mary B. Jones,
ACF/OPRE Certifying Officer.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0065]

Notice of Approval of Product Under Voucher: Material Threat Medical Countermeasure Priority Review Voucher; FABHALTA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the approval of a product redeeming a material threat medical countermeasure (MCM) priority review voucher. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to award priority review vouchers to sponsors of approved material threat MCM product applications that meet certain criteria. FDA is required to publish notice of the issuance of material threat MCM priority review vouchers as well as the approval of products redeeming a voucher. FDA has determined that FABHALTA (iptacopan) capsules, approved December 5, 2023, meets the redemption criteria.

FOR FURTHER INFORMATION CONTACT: Cathryn Lee, Center for Drug Evaluation and Research, Food and Drug

Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1394, email: Cathryn.Lee@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under section 565A of the FD&C Act (21 U.S.C. 360bbb–4a) FDA will report the issuance of material threat MCM priority review vouchers and the approval of products for which a voucher was redeemed. FDA has determined that the application for FABHALTA (iptacopan) capsules, approved December 5, 2023, meets the redemption criteria.

For further information about the material threat MCM Priority Review Voucher Program and for a link to the full text of section 565A of the FD&C Act, go to <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/21st-century-cures-act-mcm-related-cures-provisions#prv>. For further information about FABHALTA (iptacopan) capsules go to the “Drugs@FDA” website at <http://www.accessdata.fda.gov/scripts/cder/daf/>.

Dated: January 10, 2024.

Lauren K. Roth,
Associate Commissioner for Policy.
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