

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

**OVER-THE-COUNTER MONOGRAPH USER FEE COVER SHEET**

Complete Form FDA 5009 for each (1) Over-the-Counter (OTC) monograph order request and (2) facility that manufactures human OTC monograph drugs. For further guidance in completing this form, refer to the instructions. For fee schedule and payment instructions, refer to <https://www.fda.gov/industry/fda-user-fee-programs/over-counter-monograph-user-fee-program-omufa>.

<p>1. APPLICANT'S / HOLDER'S / OWNER'S / PARENT COMPANY'S NAME AND ADDRESS:</p> <p>EIN:</p> <p>DUNS Number:</p>	<p>4. SELECT THE OVER-THE-COUNTER DRUG USER FEE TYPE:</p> <p><input type="checkbox"/> OTC monograph order request (OMOR)</p> <p><input checked="" type="checkbox"/> Facility</p>
<p>2. NAME, TITLE, TELEPHONE NUMBER, AND E-MAIL ADDRESS OF APPLICANT'S/HOLDER'S/OWNER'S/PARENT COMPANY'S REPRESENTATIVE OR U.S. AGENT:</p>	
<p>3. FISCAL YEAR TO WHICH THIS PAYMENT APPLIES:</p>	

**APPLICATION INFORMATION**

5. APPLICATION NUMBER FOR OMOR:

6. PROVIDE ESTABLISHED NAME OF PRODUCT:

7. IDENTIFY THE TYPE OF OMOR SUBMISSION:

☐ Tier 1 OMOR

☐ Tier 2 OMOR

☐ Safety OMOR

**FACILITY INFORMATION**

8. PROVIDE FACILITY'S NAME, ADDRESS, FDA ESTABLISHMENT IDENTIFIER (FEI) NUMBER AND FACILITY DUNS NUMBER:

FEI Number:

Facility DUNS Number:

9. INDICATE THE TYPE OF OTC MONOGRAPH DRUG FACILITY

Does the facility qualify as a Contract Manufacturing Organization (CMO)? ☐ Yes ☐ No

**USER FEE PAYMENT INFORMATION**

10. USER FEE PAYMENT I.D. NUMBER (PIN):

11. USER FEE PAYMENT AMOUNT FOR THIS SUBMISSION:

CERTIFICATION STATEMENT:

As the responsible official or designee of the company named above, I hereby certify to the United States Food and Drug Administration that the information provided on this cover sheet is accurate and complete, to the best of my knowledge.

Making or submitting false statements on any documents submitted to FDA may constitute violations of the United States Code Title 18, Chapter 47, Section 1001 with penalties including up to \$250,000 in fines and up to 5 years imprisonment.

SIGNATURE OF AUTHORIZED REPRESENTATIVE	PRINTED NAME AND TITLE	DATE
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## Instructions for completing Form FDA 5009 (OVER-THE-COUNTER DRUG USER FEE COVER SHEET)

Form FDA 5009 is to be completed on-line at [https://userfees.fda.gov/OA\\_HTML/omufaCAcdLogin.jsp](https://userfees.fda.gov/OA_HTML/omufaCAcdLogin.jsp) for each (1) Over-the-Counter (OTC) monograph order request and (2) facility that manufactures human OTC monograph drugs. A copy of the completed form FDA 5009 must be included with Form 356(h) for an OTC monograph order request to the FDA. If you need assistance in completing the form, call 301-796-7200 or email: [userfees@fda.gov](mailto:userfees@fda.gov).

GENERAL INFORMATION
<p><b>1. APPLICANT, HOLDER OR OWNER:</b> This is the legal person or entity that owns, controls, or represents the subject of the submission (i.e., OTC monograph order request or the monograph drug facility). This field is intended to reflect the name and address of record for the applicant, holder, or owner. Note that it is not intended to reflect the physical location of a facility, unless the applicant, holder, or owner is physically located in that facility. The Employer Identification Number (EIN), also known as the Federal Employer Identification Number or the Federal Tax Identification Number, is a unique nine-digit number assigned by the Internal Revenue Service to business entities operating in the United States for the purposes of identification. The DUNS Number is issued by Dun &amp; Bradstreet, Inc. and widely used for firm identification; see <a href="http://www.dnb.com/duns-number.html">http://www.dnb.com/duns-number.html</a> for more information. Only one of these two identification number is required.</p>
<p><b>2. REPRESENTATIVE OR U.S. AGENT:</b> This provides the FDA with a person that is authorized to respond to questions on this user fee cover sheet. If this is a foreign applicant, holder, or owner, the contact person must be a U.S. agent. This field is intended to reflect the name, title, telephone number, and e-mail address of the representative or U.S. agent.</p>
<p><b>3. FISCAL YEAR:</b> Indicate the U.S. government's fiscal year (October 1 - September 30) to which this payment applies. Note that each fiscal year starts on October 1 of the previous calendar year (i.e., October 1, 2020 is the beginning of Fiscal Year 2021).</p>
<p><b>4. OVER-THE-COUNTER MONOGRAPH DRUG USER FEE TYPES:</b> Check the box to indicate the type of OTC drug user fee this cover sheet references.</p> <p><b>OTC Monograph Order Request</b> - Refer to instructions for items 5. <b>Facility</b> - Refer to instructions for item 8.</p>
OVER-THE-COUNTER MONOGRAPH ORDER REQUEST (OMOR)
<p><b>5. APPLICATION NUMBER FOR OMOR:</b> Please provide application number for the OMOR. Further information is available at <a href="https://www.fda.gov/drugs/forms-submission-requirements/electronic-regulatory-submission-and-review">https://www.fda.gov/drugs/forms-submission-requirements/electronic-regulatory-submission-and-review</a></p>
<p><b>6. PROVIDE ESTABLISHED NAME OF PRODUCT:</b> The name of the product as referenced by the application will be a validation check if and when questions arise about application of payments or for other purpose.</p>
<p><b>7. TYPE OF SUBMISSION:</b></p> <p><b>Tier 1:</b> This would include most innovations, such as new ingredients, indications, combinations, test methods, routes of administration, doses, or concentrations.</p> <p><b>Tier 2:</b> This would include a defined set of smaller, finite changes, such as standardization of doses of a finalized ingredient within a finalized monograph. I.e., (i) the reordering of existing information in the drug facts label of an OTC monograph drug; (ii) the addition of information to the other information section of the drug facts label of an OTC monograph drug, as limited by section 201.66(c)(7) of title 21, Code of Federal Regulations (or any successor regulations); (iii) modification to the directions for use section of the drug facts label of an OTC monograph drug, if such changes conform to changes made pursuant to section 505G(c)(3)(A); (iv) the standardization of the concentration or dose of a specific finalized ingredient within a particular finalized monograph; (v) a change to ingredient nomenclature to align with nomenclature of a standards-setting organization; or“(vi) addition of an interchangeable term in accordance with section 330.1 of title.</p> <p><b>Safety:</b> This would include OTC monograph order request that seeks to change the drug facts labeling of an OTC monograph drug in a way that would add to or strengthen (a) a contraindication, warning, or</p>

precaution; (b) a statement about risk associated with misuse or abuse; or (c) an instruction about dosage and administration that is intended to increase the safe use of the OTC monograph drug. Safety OMOR's do not have a fee.

#### FACILITY INFORMATION

**8. PROVIDE FACILITY NAME, ADDRESS, FDA ESTABLISHMENT IDENTIFIER (FEI) NUMBER, AND FACILITY DUNS NUMBER:** Indicate the official name of the facility and the facility's physical address. The FDA Establishment Identifier (FEI) is a unique identifier issued by FDA's Office of Regulatory Affairs. More information is available at <https://www.accessdata.fda.gov/scripts/feiportal/index.cfm?action=portal.login>. If you have questions about obtaining a FDA Establishment Identifier (FEI) number, please refer to [https://direct.fda.gov/apex/f?p=100:LOGIN\\_DESKTOP:115293335096037](https://direct.fda.gov/apex/f?p=100:LOGIN_DESKTOP:115293335096037). Please be sure to use the DUNS Number associated with the physical location of the facility (also known as the 'establishment DUNS' as distinguished from the 'registrant DUNS').

**9. TYPE OF FACILITY:** A facility that manufactures human over-the-counter monograph drug products means a foreign or domestic business or other entity that i) under one management; either direct or indirect; ii) at one geographic location or address that engaged in manufacturing or processing the finished dosage form of an OTC monograph drug. A Contract Manufacturing Organization (CMO) is an OTC monograph drug facility where neither the owner of such manufacturing facility nor any affiliate of such owner or facility sells the OTC monograph drug produced at such facility directly to wholesalers, retailers, or consumers in the United States.

#### USER FEE PAYMENT INFORMATION

**10. USER FEE PAYMENT I.D. NUMBER (PIN):** This number is automatically generated by the User Fee System. When submitting your payment, please include the PIN on the reference line on your wire transfer payment.

**11. USER FEE PAYMENT AMOUNT FOR THIS SUBMISSION:** This amount is automatically calculated by the User Fee System based on the information provided in the cover sheet. If you are remitting this payment by wire transfer, please be sure to include any additional charges imposed by your financial institution (e.g., wire transfer fee).

#### Privacy Act Notice:

This notice is provided pursuant to the Privacy Act of 1974, 5 U.S.C. 552a. The collection of this information is authorized by 21 U.S.C. 744B. FDA will use the information to assess, collect and process user fee payments, and facilitate debt collection under the Debt Collection Improvement Act. FDA may disclose information to courts and the Department of Justice in the context of litigation and requests for legal advice; to other Federal agencies in response to subpoenas issued by such agencies; to HHS and FDA employees and contractors to perform user fee services; to the National Archives and Records Administration and General Services Administration for records management inspections; to the Department of Homeland Security and other Federal agencies and contractors in order to detect or respond to system breaches; to banks in order to process payment made by credit card; to Dun and Bradstreet to validate submitter contact information, and to other entities as permitted under the Debt Collection Improvement Act. Furnishing the requested information is mandatory. Failure to supply the information could prevent FDA from processing user fee payments. Additional details regarding FDA's use of information is available online: <http://www.fda.gov/RegulatoryInformation/FOI/PrivacyAct/>.

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