POLICY AND PROCEDURES

OFFICE OF NEW DRUGS

Roles and Responsibilities of Staff in the Review (Including Collaborative Review) of Nonprescription Product Applications and Submissions under 505G of the FD&C Act

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PURPOSE

- This MAPP describes the collaborative review (defined below) between the Office of Nonprescription Drugs (ONPD) and the specific subject matter review divisions (SSMRDs) in the Office of New Drugs (OND) and other Center for Drug Evaluation and Research (CDER) offices relating to the review of pre-investigational new drug applications (PINDs), investigational new drug applications (INDs), new drug applications (NDAs), and supplemental NDAs (sNDAs) for nonprescription drugs, and submissions to FDA under section 505G of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for over-the-counter (OTC) monograph drugs.

- This MAPP also describes the roles and responsibilities of review team members and the sign-off policies and procedures for nonprescription drugs and OTC monograph drugs.

- The procedures in this MAPP are intended to ensure quality and consistency in the reviews for nonprescription NDA and OTC monograph drugs.

- This MAPP does not describe the required formal consultative interactions between ONPD and other CDER offices outside of OND, or other Centers within FDA.

- This MAPP does not address the specific conduct or content of scientific reviews.

BACKGROUND

- ONPD in OND has primary responsibility for overseeing the development, review, and regulation of nonprescription drug products marketed under an approved NDA or marketed without an approved drug application under section 505G of the FD&C Act (i.e., OTC monograph drugs).

- The review divisions in ONPD have oversight of nonprescription drug products in specific therapeutic areas.

- The ONPD review division may identify that additional therapeutic and/or subject matter expertise is needed to review data or information to support a nonprescription application or OTC monograph order. This scientific input is received through a collaborative process with one or more OND prescription clinical offices/review divisions and/or other CDER offices.

- All submissions to FDA under section 505G are referred to as "OTC monograph submissions." Examples of OTC monograph submissions that may require collaborative review include, but are not limited to, the following:

  – OTC monograph order requests (OMORs)[1]

  – Public comments to a proposed administrative order (issued either on FDA's initiative or at the request of one or more requestors)[2,3] or interim final administrative order[4]

  – Formal meeting requests and meeting packages[5]

  – Formal dispute resolution requests related to a final administrative order[6]

[1] Refer to section 744L(7) of the FD&C Act, which defines an OTC monograph order request as a request submitted under section 505G(b)(5) of the FD&C Act.
[2] Refer to section 505G(b)(1) and (2) of the FD&C Act.
[3] Refer to section 505G(b)(1) and (5) of the FD&C Act.
[4] Refer to section 505G(b)(4) of the FD&C Act.
[5] Refer to section 505G(h)(l)(1) of the FD&C Act. See also the guidance for industry *Formal Meetings Between Food and Drug Administration and Sponsors or Requestors of Over-the-Counter Monograph Drugs* (July 2026). For the most recent version of a FDA guidance, refer to the *Search for FDA Guidance Documents* webpage at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.
[6] Refer to section 505G(b)(2)(A)(iv)(III) of the FD&C Act.

- Administrative hearing requests related to a final administrative order[7]
- Responses to record requests by FDA relating to minor changes[8]

POLICY

- The ONPD, Division of Nonprescription Drugs (DNPD) staff lead the review of PINDs, INDs, NDAs, and sNDAs for nonprescription drug products (hereafter collectively referred to as applications) and OTC monograph review activities.
- When additional subject matter expertise is needed, the appropriate ONPD division will obtain input from specific subject matter review divisions (SSMRDs), including but not limited to the relevant Office of New Drugs (OND) Clinical Offices; Office of Surveillance and Epidemiology (OSE); Office of Pharmaceutical Quality (OPQ); and the Office of Translational Sciences (OTS)/Office of Biostatistics (OB) and Office of Clinical Pharmacology (OCP) (collectively referred to as the review team).
- Attachment 1 provides a general representation of the primary review responsibilities between ONPD and the SSMRDs for various subject areas.
- In general, most outreach from ONPD to SSMRDs is handled under the collaborative review process. The collaborative review process is not the same as a consultative review process. A formal consult will not be issued for collaborative reviews.[9]

COLLABORATIVE REVIEW ROLES AND RESPONSIBILITIES

Division of Regulatory Operations-Nonprescription Drugs (DRO-NPD) Chief Project Management Staff (CPMS)

- Triages and assigns a DRO-NPD Regulatory Project Manager (RPM) when a new application for a nonprescription drug or OTC monograph submission is submitted.

[7] Refer to section 505G(b)(3) of the FD&C Act.
[8] Refer to section 505G(c)(2)(A) of the FD&C Act.
[9] In situations when ONPD is collaborating with a specific OND prescription clinical review division based on the proposed indication, a consultative review may be needed for other specific questions that are best addressed by another OND prescription clinical review division, such as for a product-specific safety issue unrelated to the proposed indication.

Division of Regulatory Operations-Nonprescription Drugs (DRO-NPD) Regulatory Project Manager (RPM)

- Determines, along with the DNPD clinical reviewer, DNPD clinical team leader and DNPD Director (or Deputy Director) (as needed), the subject matter expertise that is needed

- Emails the relevant OND prescription clinical review division point of contact (POC) and SSMRD POC to request reviewer assignment(s).

- Issues information requests (IRs) to sponsors, applicants, and requestors, as appropriate.

- Serves as the POC for communications with sponsors, applicants, and requestors for the application or OTC monograph submission.

- Ensures that submissions are accurately coded in the applicable CDER electronic records keeping system (ERKS), and submits change requests, as appropriate.

- Schedules and facilitates all FDA internal and formal industry meetings consistent with applicable CDER guidance and policies[10], as needed.

- Participate in formal meetings with the sponsor, applicant, or requestor, as needed.

- Drafts, coordinates clearance of, and issues the appropriate correspondence and action letters to sponsors, applicants, and requestors.

- Coordinates clearance of administrative orders.

DNPD Director (or Deputy Director)

- Participate in team and other key meetings (e.g., filing, mid-cycle, and wrap-up) as needed.

- Participate in formal meetings with the sponsor, applicant, or requestor, as needed.

- Provides summary decisional review or concurs with cross-disciplinary team leader (CDTL) or integrated review.

- Signs correspondences for PIND and IND applications.

[10] Meetings (including face to face, formal teleconferences, and videoconferences) with the sponsor, applicant, or requestor during the review process should include members of the review team.

- Signs correspondences for OTC monograph submissions.

- Signs correspondences and action letters for NDAs and administrative orders.

OND Prescription Clinical Division Director (or Deputy Director)

- Participate in team and other key meetings (e.g., filing, mid-cycle, and wrap-up) as needed.

- Participate in formal meetings with the sponsor, applicant, or requestor, as needed.

- Provides summary review or concurs with CDTL or integrated review for new molecular entity (NME) and certain first-in-class NDAs.

OND Prescription Clinical Office Director (or Deputy Director)

- Participate in team and other key meetings (e.g., filing, mid-cycle, and wrap-up) for new molecular entity (NME) and certain first-in-class NDAs.

- Participate in formal meetings with the sponsor, applicant, or requestor, for new molecular entity (NME) and certain first-in-class NDAs as needed.

- Provides summary review or concurs with clinical division summary or integrated review for new molecular entity (NME) and certain first-in-class NDAs.

ONPD Director (or Deputy Director)

- Participate in team and other key meetings (e.g., filing, mid-cycle, and wrap-up) as needed.

- Participate in formal meetings with the sponsor, applicant, or requestor, as needed.

- Provides summary decisional review or concurs with DNPD division summary or integrated review and signs action letters for new molecular entity (NME) and certain first-in-class NDAs and certain administrative orders.

Specific Subject Matter Review Division (SSMRD)

- Participate in drafting IRs, advice letters, meeting correspondences, and action letters as applicable.

- Participate in team and other key meetings (e.g., filing, mid-cycle, and wrap-up) as needed.

- Participate in formal meetings with the sponsor, applicant, or requestor, as needed.

- Final recommendations from the SSMRD should reflect the position of the SSMRD management, and for NDAs should address history of the associated prescription drug product if applicable.

SSMRD Point of Contact (POC)[11]

- Receives the review request from the DRO-NPD RPM.

- Upon receipt of review request notifies the DRO-NPD RPM of reviewer assignments within 3 business days for formal meetings and 10 business days for NDAs.

- Provides a list of names of additional division staff (i.e., team leaders, division management and/or office management) whose participation is deemed appropriate to the DRO-NPD RPM.

PROCEDURES

1. Collaborative Review

a. Through all stages of drug product development, all review team members will proactively collaborate and provide their opinions on matters related to their expertise, as well as the suitability and appropriateness of the drug product for nonprescription use.

b. The DNPD and SSMRD reviewers draft their assigned section (if the review is integrated) or draft a separate review.

c. The DNPD and SSMRD reviewers obtain clearance through their management and share the review with the DRO-NPD RPM by the agreed upon due date.

[11] Generally, these requests will be directed to the receiving ORO staff (CPMS or other ORO staff) or CDER Office contact. The SSMRD POC will serve as the point of contact for the DRO-NPD RPM unless other SSMRD staff are designated as the SSMRD POC.

2. Advisory Committee Meetings

Nonprescription drug applications and OTC monograph orders may be considered for review by an FDA advisory committee panel that includes the full Nonprescription Drugs Advisory Committee (NDAC). Depending on the subject matter, the review team may choose to include a full committee from the representative SSMRD or certain members of those committees who can complement the discussion with their particular subject matter expertise. The meeting will be chaired by the NDAC chairperson.

a. Members of the review team (ONPD and SSMRD) will collaborate in producing the AC backgrounder and slides, as well as participate in AC meetings as needed.

3. Postapproval Oversight of Nonprescription Drug Products Marketed Under an Approved NDA

a. Drug products approved under a nonprescription NDA will remain the responsibility of ONPD.

b. Efficacy supplements, labeling supplements, and chemistry, manufacturing, and controls (CMC) supplements with labeling for nonprescription drug products approved under an NDA will remain the responsibility of ONPD.

c. CMC supplements for nonprescription drug products approved under an NDA will remain the responsibility of OPQ.

d. If an applicant requests additional nonprescription claims or variations on the original claim for a nonprescription drug approved under an NDA/sNDA, the review of such requests will be conducted by ONPD, in collaboration with the appropriate SSMRDs. The review will proceed as outlined in the Procedures section of this MAPP.

e. ONPD will review postmarketing periodic safety reports and evaluate the need for revisions to the nonprescription drug product labeling.

f. Whenever feasible, the same SSMRD reviewers and ONPD reviewers who served on the initial review team should be assigned to review postapproval supplements.

4. Resolution of Differing Professional Opinions

a. If there are disagreements between review team members, the disagreements will be resolved as described in MAPP 4151.8 *Equal Voice: Collaboration and Regulatory Policy Decision-Making in CDER* or as described in FDA Staff Manual Guides (SMG) 9010.1, 9010.2, and 9010.3.

REFERENCES

- FDA Staff Manual Guide 9010.1 – *Scientific Dispute Resolution at FDA* (05/21/2021).
- FDA Staff Manual Guide 9010.2 – *Cross Center Dispute Resolution at the FDA* (06/21/2019).
- FDA Staff Manual Guide 9010.3 – *Authorship Dispute Resolution at FDA* (01/14/2021).
- CDER MAPP 4151.8 (Rev. 2), *Equal Voice: Collaboration and Regulatory Policy Decision-Making in CDER* (08/12/2025).

DEFINITIONS

- **Administrative Order:** Under the process set forth in section 505G(b) of the FD&C Act, FDA has the authority to issue an administrative order (proposed, interim final, or final) that adds, removes, or changes generally recognized as safe and effective (GRASE) conditions for an OTC drug monograph.
- **Collaborative Review:** One or more divisions other than the lead nonprescription division contribute resources to an application or OTC monograph review team to review a specific portion of the submission (e.g., chemistry, manufacturing, and controls; statistics; clinical pharmacology; clinical; human factors).
- **Consultative Review:** One or more CDER offices or Centers (e.g., CDRH) within FDA that require a formal consult process (e.g., Intercenter Consult Request (ICCR)) for expertise that resides in another office or center.
- **Consumer Studies:** Studies to evaluate how consumers will use the drug product in a nonprescription setting without the supervision of a health care provider. Consumer behavior studies may include: label comprehension, self-selection, actual use, and human factors studies.
- **Direct-to-Nonprescription:** Nonprescription marketing of a drug product that was never previously marketed as a prescription drug product.
- **First-in-Class Nonprescription Drug Product:** A proposed drug product that, if approved, would be the first in its pharmacological class to be marketed without

a prescription or that would be intended for an indication not applicable to any legally marketed nonprescription drug product.

- **Human Factors Study:** A study conducted to assess the adequacy of the nonprescription combination product user interface design to eliminate or mitigate potential use-related hazards.

- **New Molecular Entity:** A new molecular entity is an active ingredient that contains no active moiety that has been previously approved by the FDA in an application submitted under section 505 of the Federal Food, Drug, and Cosmetic Act or has been previously marketed as a drug in the United States.

- **Actual Use Study:** A clinical trial to evaluate the use of the drug product under "real world" conditions to identify any issues with use that have not previously been recognized, and to confirm that consumers can self-diagnose and treat themselves appropriately without the intervention of a health care professional.

- **Nonprescription Drug Product:** A drug product approved for marketing which can be used safely and effectively by consumers without the supervision of a health care professional and does not meet the criteria for prescription-only dispensing.

- **Label Comprehension Study:** A study to evaluate the extent to which consumers understand the information on the proposed nonprescription drug product labeling. In such studies, no drug product is dispensed to subjects. Such a study is not a clinical investigation as defined under 21 CFR 312.3(b).

- **OTC Monograph Drug:** A nonprescription drug without an approved drug application which is governed by the provision of section 505G of the FD&C Act. An OTC drug monograph establishes conditions, such as active ingredients, uses (indications), doses, routes of administration, labeling, and testing, under which an OTC drug in a given therapeutic category (e.g., sunscreen, antacid) is generally recognized as safe and effective (GRASE) for its intended use.

- **Prescription Drug Product:** A drug product approved for marketing that can be obtained only with a prescription from an appropriately licensed health care professional.

- **Prescription-to-Nonprescription Switch:** A change in marketing status through the NDA process from a prescription drug product to a nonprescription drug product. There are two types of prescription-to-nonprescription switches: full or partial. A full switch, via submission of an efficacy supplement, is where the drug product switches all conditions of use in their entirety (e.g., indications, strengths). Upon approval, the drug will only be available as a nonprescription drug. A partial switch, via submission of an NDA, is where the drug product

switches some of the conditions of use (e.g., indications) to nonprescription, while retaining others within a prescription status. The FD&C Act does not permit the simultaneous marketing of the same active ingredient in prescription and nonprescription drug products unless a meaningful difference exists between the two products. There are certain drug products for which such simultaneous marketing is permitted due to such meaningful differences between the prescription and nonprescription drug products (sometimes referred to as a "partial switch" of the drug product to nonprescription status).

- **Review Team:** Typically includes ONPD/DNPD and SSMRD reviewers from clinical, biostatistics, clinical pharmacology, pharmacology/toxicology, and product quality; team leaders, cross-discipline team leads, ORO staff, and the office/division director(s) (or designees). Additional roles or disciplines may be included as needed, based on the nature or content of the application.

- **Self-Selection Study:** A study to assess the ability of consumers to apply drug labeling information to their personal health situation to make correct decisions about whether or not it is appropriate for them to use a drug product.

- **Specific Subject Matter Review Division (SSMRD):** The CDER office or OND prescription clinical review division with primary oversight of a group of prescription drug products directed at physiologically categorized diseases (e.g., cardiovascular drug products).

EFFECTIVE DATE

- This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
01/15/1997 07/12/2007	R1	Revised to reflect OND reorganization and assignment of nonprescription drug product applications to the Office of Nonprescription Drugs (ONPD).
06/25/2018	R2	In addition to editorial changes, names of offices and divisions were updated.
10/20/2026	R3	Updated to align with current OND organizational structure, applicable user fee agreement (UFA) commitments, and CDER workflow procedures and best practices.

ATTACHMENT 1: COLLABORATIVE REVIEW ASSIGNMENTS

Subject	Primary Review Responsibility
Chemistry, Manufacturing, and Controls	SSMRD[1]
Clinical Efficacy[2]	SSMRD
Clinical Pharmacology	SSMRD[3]
Clinical Safety Controlled safety data from efficacy trials From consumer studies From postmarketing data and information	 SSRMD ONPD ONPD
Consumer Studies: Label comprehension Self-selection Actual use Human Factors	 ONPD ONPD ONPD SSMRD[4]
Drug Facts Labeling (DFL)	ONPD[5]
Pharmacology and Toxicology	ONPD
Statistics From clinical efficacy trial From consumer studies	 SSMRD[6] SSMRD[7]

[1] Office of Pharmaceutical Quality (OPQ).
[2] SSMRD assignment is based on the aligned therapeutic OND prescription clinical review division. Generally, SSMRD will review clinical efficacy studies and, where applicable, will provide summary of efficacy that supported prescription approval. ONPD will have primary review responsibility for clinical simulation studies for sunscreen and antiseptic nonprescription NDA and OTC monograph drugs.
[3] Assignment is based on the aligned therapeutic Office of Translational Sciences (OTS)/Office of Clinical Pharmacology (OCP) division.
[4] Office of Safety and Epidemiology (OSE)/Division of Medication Error Prevention and Analysis (DMEPA).
[5] DFL may also be reviewed by DMEPA and/or the aligned therapeutic OND prescription clinical review division.
[6] Assignment is based on the aligned therapeutic OTS/Office of Biostatistics (OB) division.
[7] OTS/OB/Division of Biometrics VII (DBVII – Safety).