

FDA's Expanded Access Contact Information

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[Forms \(http://wcms-internet.fda.gov/news-events/expanded-access/expanded-access-how-submit-request-forms\)](http://wcms-internet.fda.gov/news-events/expanded-access/expanded-access-how-submit-request-forms)

Key Contact Information

1. During Normal Business Hours (8 a.m. - 4:30 p.m. ET, weekdays)

For **specific questions** during normal business hours:

- **Investigational drugs:** 301-796-3400 or druginfo@fda.hhs.gov (<mailto:druginfo@fda.hhs.gov>) [CDER's Division of Drug Information], or contact the appropriate review division, if known
- **Investigational medical devices:** 301-796-7100 or DICE@fda.hhs.gov (<mailto:DICE@fda.hhs.gov>) [CDRH's Division of Industry and Consumer Education]
- **Investigational biologics:** 240-402-8020 or 800-835-4709 or industry.biologics@fda.hhs.gov (<mailto:industry.biologics@fda.hhs.gov>) [CBER's Office of Communication, Outreach and Development]

For **general questions**, or if you are unsure of who to contact, contact the Patient Affairs Staff at 301-796-8460 or patientaffairs@fda.hhs.gov (<mailto:patientaffairs@fda.hhs.gov>).

2. After 4:30 p.m. ET weekdays and all day on weekends

For **emergency requests** for all medical products (drugs, biologics, and medical devices) contact **FDA's Emergency Call Center** at 866-300-4374.

Mailing Addresses for Expanded Access Applications

Drug Products	Biologic Products	Medical Devices
<i>Individual Patient IND Requests and Follow-up Reports submitted by a licensed physician using FDA Form 3926</i>	<i>Individual Patient IND Requests and Follow-up Reports submitted by a licensed physician using FDA Form 3926</i>	<i>Individual Patient Expanded Access Requests and Follow-up Reports (including Emergency Use Reports)</i>
Food and Drug Administration Center for Drug Evaluation and Research Central Document Room ATTN: [appropriate Review Division] "EXPANDED ACCESS SUBMISSION" 5901-B Amundson Ave. Beltsville, Md. 20705-1266	Food and Drug Administration Center for Biologics Evaluation and Research Document Control Center 10903 New Hampshire Avenue Bldg. 71, Rm. G112 Silver Spring, MD 20993-0002	Food and Drug Administration Center for Devices and Radiological Health Document Mail Center 10903 New Hampshire Avenue Bldg. 66, Rm. G609 Silver Spring, MD 20993-0002 If an IDE exists for the device, include the IDE number in the request. Learn more about medical device expanded access here (/medical-devices/investigational-device-exemption-ide/expanded-access-medical-devices).

For other submission options, contact FDA using the information below. Please call or e-mail before faxing documents.

FDA Centers and Review Divisions

Centers / Review Divisions	Telephone Number / email	Fax Number call review division before sending fax
Center for Biologic and Evaluation Research (CBER) Office of Communication, Outreach and Development	240-402-8020 or 800-835-4709 or industry.biologics@fda.hhs.gov (mailto:industry.biologics@fda.hhs.gov)	
Center for Devices and Radiological Health (CDRH) Division of Industry and Consumer Education	301-796-7100 or DICE@fda.hhs.gov (mailto:DICE@fda.hhs.gov)	
Center for Drug Evaluation and Research (CDER)		
• Division of Drug Information (DDI)	301-796-3400 or druginfo@fda.hhs.gov (mailto:druginfo@fda.hhs.gov)	

Centers / Review Divisions	Telephone Number / email	Fax Number call review division before sending fax
<ul style="list-style-type: none"> Antimicrobial Products (/about-fda/about-center-drug-evaluation-and-research/office-antimicrobial-products-oap) (anti-infective, transplant, ophthalmology, antiviral products) 	301-796-1300	301-796-9887
<ul style="list-style-type: none"> Oncology Products 1 (/about-fda/about-center-drug-evaluation-and-research/division-oncology-products-1-dop1) (Breast, Gynecologic/Supportive care, Genitourinary) 	301-796-2330	301-796-9845
<ul style="list-style-type: none"> Oncology Products 2 (/about-fda/about-center-drug-evaluation-and-research/division-oncology-products-2-dop2) (Gastrointestinal, Lung/Head&Neck, Neuro-oncology/Rare Cancers/Solid Tumor Pediatric Malignancies, Melanoma/Sarcoma) 	301-796-2320	301-796-9849
<ul style="list-style-type: none"> Hematology Products (/about-fda/about-center-drug-evaluation-and-research/division-hematology-products-dhp) (Benign Hematology, Hematology Malignant, Hematology Support) 	301-796-7550	301-796-9845
<ul style="list-style-type: none"> Bone, Reproductive and Urologic Products (/about-fda/about-center-drug-evaluation-and-research/division-bone-reproductive-and-urologic-products-dbrup) 	301-796-2130	301-796-9897
<ul style="list-style-type: none"> Medical Imaging Products 	301-796-2050	301-796-9848

Centers / Review Divisions	Telephone Number / email	Fax Number call review division before sending fax
<ul style="list-style-type: none"> Gastroenterology and Inborn Errors Products (/about-fda/about-center-drug-evaluation-and-research/division-gastroenterology-and-inborn-errors-products-dgiep) 	301-796-2120	301-796-9904
<ul style="list-style-type: none"> Anesthesia, Analgesia, and Addiction Products (/about-fda/about-center-drug-evaluation-and-research/division-anesthesia-analgesia-and-addiction-products-daaap) 	301-796-2280	301-796-9723
<ul style="list-style-type: none"> Metabolism and Endocrinology Products (/about-fda/about-center-drug-evaluation-and-research/division-metabolism-and-endocrinology-products-dmep) 	301-796-2290	301-796-9712
<ul style="list-style-type: none"> Pulmonary, Allergy and Rheumatology Products (/about-fda/about-center-drug-evaluation-and-research/division-pulmonary-allergy-and-rheumatology-products-dparp) 	301-796-2300	301-796-9728
<ul style="list-style-type: none"> Dermatology and Dental Products (/about-fda/about-center-drug-evaluation-and-research/division-dermatology-and-dental-products-dddp) 	301-796-2110	301-796-9895
<ul style="list-style-type: none"> Cardiovascular and Renal Products (/about-fda/about-center-drug-evaluation-and-research/office-drug-evaluation-i-division-cardiovascular-and-renal-products-dcarp) 	301-796-2240	301-796-9838

Centers / Review Divisions	Telephone Number / email	Fax Number call review division before sending fax
<ul style="list-style-type: none"> Neurology Products (/about-fda/about-center-drug-evaluation-and-research/office-drug-evaluation-i-division-neurology-products-dnp) 	301-796-2250	301-796-9840
<ul style="list-style-type: none"> Psychiatry Products (/about-fda/about-center-drug-evaluation-and-research/office-drug-evaluation-i-division-psychiatry-products-dpp) 	301-796-2260	301-796-9842

Resources For You

- Visit the Expanded Access (Compassionate Use) main page (/expanded-access-compassionate-use-o)