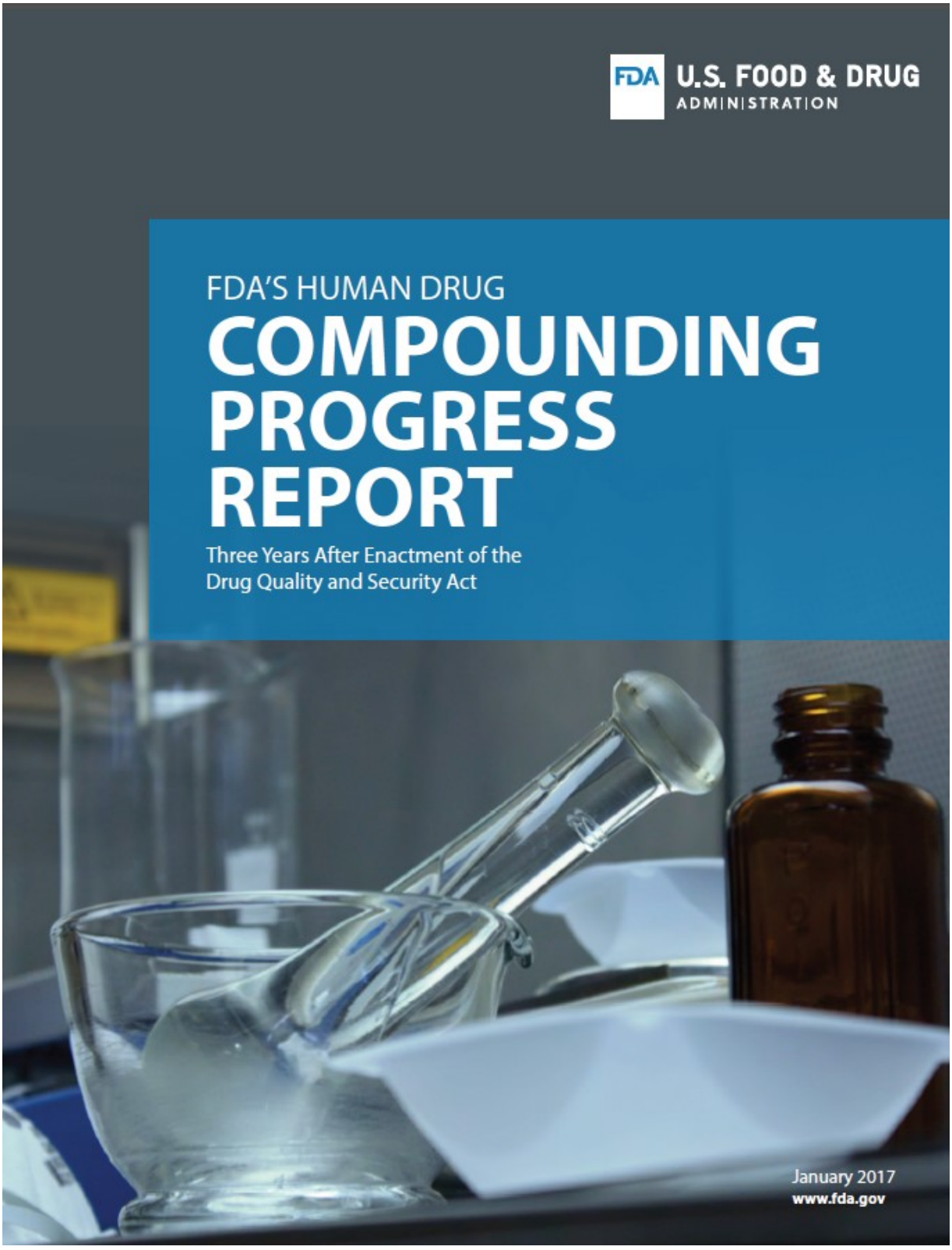
Human Drug Compounding



FDA's Human Drug Compounding Progress Report: Three Years After Enactment of the Drug Quality and

Security Act (January 2017)
Download PDF (/media/102493/download)
Text Version (/drugs/compounding/fdas-human-drug-compounding-progress-report-three-years-after-enactment-drug-quality-and-security)

Compounding is generally a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility (/drugs/compounding/information-outsourcing-facilities), a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. Although compounded drugs can serve an important medical need for certain patients, they also present a risk (http://wayback.archive-it.org/7993/20170111235218/http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm107836.htm) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) to patients.

FDA's compounding program aims to protect patients from unsafe, ineffective and poor quality compounded drugs, while preserving access to lawfully-marketed compounded drugs for patients who have a medical need for them.

Questions? Email FDA's compounding team at compounding@fda.hhs.gov (mailto:compounding@fda.hhs.gov).

Compounding Quality Center of Excellence (/drugs/human-drug-compounding/compounding-quality-center-excellence)

Learn more about FDA's efforts to improve the quality of compounded drugs, primarily those made at outsourcing facilities, through the Compounding Quality Center of Excellence (/drugs/human-drug-compounding/compounding-quality-center-excellence).

Compounding Laws and Policies (/drugs/compounding/compounding-laws-and-policies)

Find information about federal law and FDA policies that apply to compounding and other activities compounders undertake. Read section 503A (/drugs/compounding/section-503a-federal-food-drug-and-cosmetic-act) and section 503B (/drugs/compounding/text-compounding-quality-act) of the Federal Food, Drug, and Cosmetic Act. Learn more about federal law provisions that apply to human drug compounding (/drugs/compounding/fdc-act-provisions-apply-human-drug-compounding) and FDA policies on compounding and other related activities (/drugs/compounding/drug-production-activities-pharmacies-physicians-federal-facilities-and-outsourcing-facilities). Find a list of compounding policy documents (/drugs/compounding/regulatory-policy-information) and information about the Pharmacy Compounding Advisory Committee (/pharmacy-compounding-advisory-committee). Also, find clarifications (/drugs/guidance-compliance-regulatory-information/fda-clarifies-compounding-policies) on FDA's policies.

Compounding Oversight and Compliance Actions (/drugs/compounding

/compounding-oversight)

Find links to compounding inspections, recalls, and other actions (/drugs/compounding/compounding-inspections-recalls-and-other-actions), as well as descriptions of some of the documents and actions involved in FDA oversight of compounding (/drugs/compounding/fda-compounding-documents-and-actions). Learn about the risks (/drugs/compounding/compounding-risk-alerts) associated with certain compounded drugs. Also, find answers to frequently asked questions about FDA inspections of compounders (/drugs/compounding/compounding-inspections-frequently-asked-questions).

Watch a webinar (https://www.youtube.com/watch?v=gXXz4o0RDeM) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) to learn why cleanrooms and cleanroom behaviors are important for preventing insanitary conditions that can adversely impact the quality and safety of drug products.

Information for Outsourcing Facilities (/drugs/compounding/information-outsourcing-facilities)

Find general information for outsourcing facilities (/drugs/compounding/information-outsourcing-facilities), as well as a list of currently registered outsourcing facilities (/drugs/human-drug-compounding/registered-outsourcing-facilities). Thinking of registering as an outsourcing facility? Find answers to frequently asked questions for entities considering registration (/drugs/compounding/questions-and-answers-related-guidance-entities-considering-whether-register-outsourcing-facilities), information on facility fees (http://www.fda.gov/ForIndustry/UserFees/HumanOutsourcingFacilityUserFee/default.htm) and how to register and submit product reporting information (/drugs/drug-registration-and-listing/human-drug-compounding-registration-and-product-reporting-procedures) to FDA.

Watch a webinar (https://www.youtube.com/watch?v=gXXz4o0RDeM) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) to learn why cleanrooms and cleanroom behaviors are important for preventing insanitary conditions that can adversely impact the quality and safety of drug products.

Bulk Drug Substances Used in Compounding (/drugs/human-drug-compounding/bulk-drug-substances-used-compounding)

Find information on using bulk drug substances under sections 503A (/drugs/human-drug-compounding/bulk-drug-substances-used-compounding-under-section-503a-fdc-act) and 503B (/drugs/human-drug-compounding/bulk-drug-substances-used-compounding-under-section-503b-fdc-act) of the Federal Food, Drug, and Cosmetic Act. FDA is working to develop the 503A bulks list and 503B bulks list (https://www.fda.gov/media/120692/download), which will be updated on an ongoing basis as the agency evaluates bulk drug substances nominated for these lists. Find information to know your bulks supplier (/drugs/human-drug-compounding/fda-compounders-know-your-bulks-

supplier) because compounding from bulk drug substances presents risks to patients.

Information for Consumers and Health Care Professionals (/drugs/compounding/consumer-and-health-care-professional-information)

Find resources for consumers (/drugs/human-drug-compounding/consumer-and-health-care-professional-information) who use compounded medicines and health care professionals (/drugs/human-drug-compounding/consumer-and-health-care-professional-information) who prescribe compounded medicine, including answers to frequently asked questions and how to report adverse events and product complaints to FDA.

Information for States (/drugs/compounding/human-drug-compounding-information-states)

Find information regarding FDA and state collaboration (/drugs/human-drug-compounding/compounding-information-states) to oversee compounding, as well as resources for state regulators, including information on the standard Memorandum of Understanding Addressing Certain Distributions of Compounded Drugs (/drugs/human-drug-compounding/memorandum-understanding-addressing-certain-distributions-compounded-drugs).

Compounding Research (/drugs/human-drug-compounding/compounding-research)

Find information about external partnerships for compounding research (/drugs/human-drug-compounding/compounding-research).