

[FDA Warning Letters Tracker](#)

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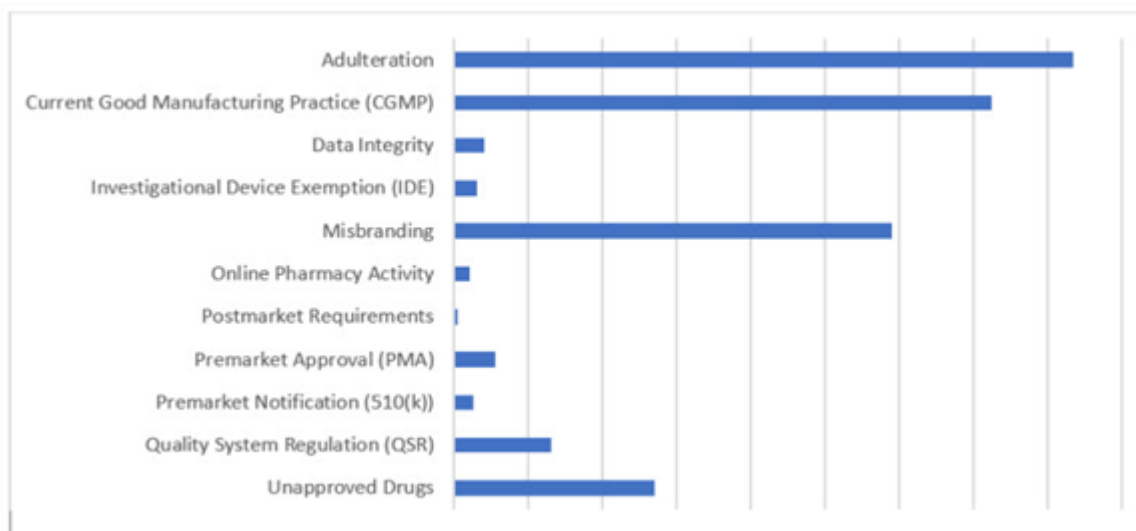
This tracker is intended as a tool to assist attorneys representing drug and medical device companies who need to monitor trends in Food and Drug Administration (FDA) enforcement activity affecting their clients. This tracker highlights selected drug and medical device-focused warning letters issued by the FDA in response to FDA's determination that a manufacturer has violated, or potentially violated, applicable requirements of the Food, Drug, and Cosmetics Act (FDCA), FDA regulations, or agency guidance. It also highlights warning letters for products related to coronavirus disease (COVID-19).

Warning letter recipients are given the opportunity to respond, voluntarily, to FDA, correct the issues highlighted by the FDA, and comply with the referenced reporting requirements. If the manufacturer does not voluntarily resolve the issues identified by FDA in the warning letter, FDA may elect to pursue further administrative or regulatory enforcement actions, including but not necessarily limited to, recall, seizure, injunction, administrative detention, civil money penalties, and/or prosecution.

For information about FDA drug regulatory activity, see [FDA Drug Regulatory Activity Tracker](#). For information about FDA medical device regulatory activity, see [FDA Medical Device Regulatory Activity Tracker](#). For information about HHS OIG fraud and abuse (anti-kickback) Advisory Opinions affecting the drug and medical device industries, see [Drug and Medical Device OIG Advisory Opinions Tracker](#). For additional information about FDA's approach to warning letters, see [FDA Regulatory Procedures Manual Ch. 4](#).

FDA Warning Letter Enforcement Trends (1/1/19 to 3/5/20)

Note: Animal, cosmetics, dietary supplements, food, and tobacco (including e-cigarette) products are not included in this summary.



Source: FDA. This graphic is intended as a relative comparison of FDA warning letter enforcement activity for the areas identified and the time specified.

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Drug and Medical Device Warning Letters (posted by FDA 5/1/19 to 3/10/20)

Note: Animal products (drugs, dietary supplements, and devices) and dietary supplements for human use are not included in this summary.

Product	FDCA Provisions Cited	Recipient	Date of Letter
Products Related to Coronavirus Disease 2019 (COVID-19)	Unapproved drugs Misbranding	Quinessence Aromatherapy LTD	3/6/20
Products Related to Coronavirus Disease 2019 (COVID-19)	Unapproved drugs Misbranding	GuruNanda LLC	3/6/20
Products Related to Coronavirus Disease 2019 (COVID-19)	Unapproved drugs Misbranding	Colloidal Vitality LLC/Vital Silver	3/6/20
Products Related to Coronavirus Disease 2019 (COVID-19)	Unapproved drugs Misbranding	Xephyr, LLC dba N-Ergetics	3/6/20
Products Related to Coronavirus Disease 2019 (COVID-19)	Unapproved drugs Misbranding	Vivify Holistic Clinic	3/6/20
Products Related to Coronavirus Disease 2019 (COVID-19)	Unapproved drugs Misbranding	The Jim Bakker Show	3/6/20
Products Related to Coronavirus Disease 2019 (COVID-19)	Unapproved drugs Misbranding	Herbal Amy Inc	3/6/20
Pharmaceuticals	Misbranding	Outlook Pharmaceuticals, Inc.	2/21/20
Pharmaceuticals	Misbranding	Mikart LLC	2/21/20
Pharmaceuticals	CGMP Adulteration	LeeSar, Inc.	2/18/20
Pharmaceuticals	CGMP Adulteration	Essnd Global	2/14/20
Pharmaceuticals	CGMP Adulteration	Yibin Lihao Bio-technical Co., Ltd.	2/13/20
Pharmaceuticals	CGMP Adulteration	JHS Svendgaard Hygiene Products Ltd	2/13/20
Medical Devices	CGMP QSR Adulteration	Biomedix WAI	2/12/20
Pharmaceuticals	CGMP Adulteration	Chemland Co., Ltd.	2/11/20
Pharmaceuticals	CGMP Adulteration	KVK-Tech, Inc	2/11/20
Pharmaceuticals	CGMP Adulteration	Acino Products, LLC	2/10/20
Medical Devices	CGMP QSR Adulteration	Unetixs Vascular, Inc.	2/4/20
Pharmaceuticals	CGMP Adulteration	Guangzhou Tinci Materials Technology Co., Ltd.	1/23/20
Medical Devices	Adulteration Misbranding	CPAPNEA Medical Supply	1/22/20

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	Lacks PMA and/or 510(k)		
Pharmaceuticals	CGMP Adulteration	Sunstar Guangzhou Ltd.	1/22/20
Medical Devices	Investigational Device Exemption (IDE) Premarket Approval (PMA) Misbranding	Draegar Medical Systems, Inc.	1/17/20
Pharmaceuticals	CGMP Adulteration	Dental-Kosmetik GmbH & Co. KG	1/16/20
Pharmaceuticals	CGMP Adulteration Unapproved drugs Misbranding Data integrity	Zhuhai Aofute Medical Technology Co., Ltd.	1/9/20
Pharmaceuticals	GGMP Adulteration	Cosmelab Co Ltd	1/9/20
Pharmaceuticals	CGMP Adulteration	Huaian Zongheng Bio-Tech Co., Ltd	1/9/20
Pharmaceuticals	Investigational Plan	James Findling	12/31/19
Medical Devices	Premarket Approval (PMA) Adulteration Investigational Device Exemption (IDE) Misbranding	Vevazz LLC	12/26/19
Pharmaceuticals	CGMP Adulteration	Apollo Health And Beauty Care, Inc.	12/23/19
Medical Devices	CGMP QSR Adulteration Misbranding	Jiangsu JDC Medical Devices Co., Ltd.	12/19/19
Pharmaceuticals	CGMP Adulteration Unapproved drugs	CGA Limited	12/19/19
Pharmaceuticals	CGMP Adulteration	Health Pharma USA LLC	12/18/19
Pharmaceuticals	CGMP Adulteration Unapproved drugs	Cross Brands Contract Filling, LLC	12/17/19
Pharmaceuticals	CGMP Adulteration	GPT Pharmaceuticals Private Ltd	12/17/19
Pharmaceuticals	CGMP Adulteration	Baja Fur S.A. de C.V.	12/13/19
Medical Devices	Premarket Approval (PMA) Adulteration Investigational Device Exemption (IDE) Misbranding	Curewave Lasers LLC	12/12/19
Pharmaceuticals	Unapproved drugs Misbranding	Soaptronic LLC	12/12/19
Medical Devices	Adulteration QSR	Conformis Inc.	12/10/19
Pharmaceuticals	CGMP Adulteration	Pharmalab Enterprises, Inc.	12/10/19

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Medical Devices	Premarket approval (PMA) Adulteration Misbranding	Zona Health Inc.	12/6/19
Pharmaceuticals	CGMP Adulteration	Wild Child WA Pty Ltd.	12/6/19
Pharmaceuticals	CGMP Adulteration Unapproved drugs	Tismor Health and Wellness Pty Limited	12/5/19
Pharmaceuticals	CGMP Adulteration Unapproved drugs	Henan Kangdi Medical Devices Co. Ltd	12/3/19
Pharmaceuticals	Misbranding	Alkermes, Inc.	12/2/19
Pharmaceuticals	CGMP Adulteration	Teligent Pharma, Inc.	11/26/19
Pharmaceuticals Cannabidiol (CBD)	Unapproved drugs Misbranding	Noli Oil, LLC	11/22/19
Pharmaceuticals Cannabidiol (CBD)	Unapproved drugs Misbranding	Bella Rose Labs	11/22/19
Pharmaceuticals Cannabidiol (CBD)	Unapproved drugs Misbranding	Sunflora, Inc./The CBD Store, LLC dba Your CBD Store	11/22/19
Pharmaceuticals Cannabidiol (CBD)	Unapproved drugs Misbranding	Infinite Product Company LLLP DBA Infinite CBD	11/22/19
Pharmaceuticals Cannabidiol (CBD)	Unapproved drugs Misbranding	Whole Leaf Organics, LLC	11/22/19
Pharmaceuticals Cannabidiol (CBD)	Unapproved drugs Misbranding	Mr. Pink Collections, LLC	11/22/19
Pharmaceuticals Cannabidiol (CBD)	Unapproved drugs Misbranding	KOI CBD LLC	11/22/19
Pharmaceuticals	CGMP Adulteration	OHM Pharma, Inc.	11/19/19
Pharmaceuticals	Unapproved drugs Misbranding	EPH Technologies, Inc.	11/18/19
Medical Devices	Adulteration QSR	American Contract Systems, Inc.	11/9/19
Pharmaceuticals	CGMP Adulteration QSR	A.P. Deauville, LLC	11/8/19
Pharmaceuticals	CGMP Adulteration	Apothecus Pharmaceutical Corp.	11/8/19
Pharmaceuticals	Receipt and delivery of adulterated drugs	Greenbrier International, Inc. dba Dollar Tree	11/6/19
Pharmaceuticals	CGMP Adulteration Unapproved drugs	Unipharma, LLC	11/6/19
Pharmaceuticals	CGMP Adulteration	Mylan Laboratories Limited - Unit 8	11/5/19
Pharmaceuticals	CGMP Adulteration	Swabplus, L.P.	10/31/19
Pharmaceuticals	CGMP Adulteration	Cadila Healthcare Limited	10/29/19
Medical Devices	CGMP QSR	Silfradent Srl	10/28/19

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	Adulteration Misbranding		
Pharmaceuticals	CGMP Adulteration QSR Unapproved drugs Misbranding	Torrent Pharma Inc.	10/28/19
Pharmaceuticals	CGMP Adulteration Unapproved drugs	MSM Nutraceuticals, LLC dba MSM Health Solutions	10/24/19
Pharmaceuticals	CGMP Adulteration	PETNET Solutions Inc.	10/17/19
Pharmaceuticals	Illegal online pharmacy activity Misbranding Unapproved drugs	Meds4U	10/16/19
Pharmaceuticals	Unapproved drugs Misbranding	Rooted Apothecary LLC	10/10/19
Pharmaceuticals	CGMP	Sofie Co., dba Sofie	10/10/19
Medical Devices	Adulteration QSR	Denterprise International, Inc.	10/9/19
Pharmaceuticals	CGMP Adulteration	Coral Pharmaceuticals LTD	10/9/19
Pharmaceuticals	CGMP Adulteration	Torrent Pharmaceuticals Limited	10/8/19
Pharmaceuticals	CGMP Adulteration Unapproved drugs Misbranding Listing obligations	Herbal Doctor Remedies	10/4/19
Pharmaceuticals	CGMP Adulteration Data integrity	Bingbing Pharmaceutical Co., Ltd	10/3/19
Pharmaceuticals	CGMP Adulteration	Glenmark Pharmaceuticals Limited	10/3/19
Pharmaceuticals	CGMP Adulteration Unapproved drugs Misbranding	The Skin Atelier, Inc. d.b.a. Skinprint	10/1/19
Pharmaceuticals	CGMP Adulteration	LNK International, Inc.	9/26/19
Pharmaceuticals	Listing obligations	NuCare Pharmaceuticals Inc.	9/26/19
Medical Devices	CGMP QSR Adulteration Misbranding	ITL Asia Pacific Sdn Bhd	9/25/19
Pharmaceuticals	CGMP Adulteration Unapproved drugs	Dercher Enterprises, Inc., DBA Gordon Laboratories	9/13/19
Pharmaceuticals	Misbranding	Galt Pharmaceuticals, LLC	9/13/19
Pharmaceuticals	CGMP Adulteration	Dermameal Co., Ltd.	9/12/19
Pharmaceuticals	Unapproved drugs Misbranding	Herbal Healer Academy, Inc.	9/12/19

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Pharmaceuticals	CGMP Adulteration QSR	Lohxa LLC	9/10/19
Pharmaceuticals	CGMP	Jiangsu NHWA Pharmaceutical Co., Ltd.	9/10/19
Pharmaceuticals	CGMP	Lupin Limited	9/10/19
Pharmaceuticals	Illegal online pharmacy activity Misbranding Unapproved drugs	Divyata	9/6/19
Pharmaceuticals	Illegal online pharmacy activity Misbranding Unapproved drugs	Euphoria Healthcare Pvt Ltd.	9/6/19
Pharmaceuticals	Illegal online pharmacy activity Misbranding Unapproved drugs	JCM Dropship	9/6/19
Medical Devices	CGMP QSR Adulteration	Won Industry Co. LTD	8/29/19
Pharmaceuticals	CGMP Adulteration Misbranding Unapproved drugs	Hangzhou Badi Daily Use Chemical Company	8/29/19
Pharmaceuticals	501(j) / refusal of inspection	Shanghai Institute of Pharmaceutical Industry	8/29/19
Pharmaceuticals Biologics	Unapproved drugs CGMP	Stemell Inc.	8/28/19
Pharmaceuticals	Misbranding Unapproved drugs	Sportron International, Inc.	8/23/19
Pharmaceuticals	CGMP Adulteration	Polimeros y Servicios S.A.	8/22/19
Pharmaceuticals	CGMP Adulteration Misbranding	Haw Par Healthcare Limited	8/19/19
Pharmaceuticals	Misbranding	Metuchen Pharmaceuticals, LLC	8/16/19
Pharmaceuticals	CGMP Adulteration Data integrity	Enprani Co., Ltd.	8/15/19
Pharmaceuticals	CGMP Adulteration Misbranding	Ningbo Pulisi Daily Chemical Products Co., Ltd	8/13/19
Pharmaceuticals	CGMP Adulteration	Yino, Inc.	8/12/19
Pharmaceuticals	CGMP Adulteration	Lantech Pharmaceuticals Limited	8/8/19
Pharmaceuticals	Unapproved drugs Misbranding	Let's Talk Health, Inc.	8/6/19
Pharmaceuticals	CGMP Adulteration	Deva Holding AS – Cerkezkoy Subsei	8/6/19
Medical Devices	Adulteration CGMP QSR	TALON, an S & S Technology Company	8/2/19

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Pharmaceuticals	CGMP Adulteration	Emcure Pharmaceuticals Limited	8/2/19
Pharmaceuticals	CGMP Adulteration Misbranding QSR Data integrity	NingBo Huize Commodity Co., Ltd.	8/2/19
Pharmaceuticals	Adulteration	Sharp Drugs, Inc. dba Island Drug and Surgical	8/2/19
Pharmaceuticals	CGMP Adulteration Unapproved drugs	TG United, Inc.	8/1/19
Medical Devices	Adulteration QSR CGMP	Polymer Technology Systems, Inc.	7/31/19
Pharmaceuticals	CGMP Adulteration Misbranding	Spectrum Laboratory Products, Inc.	7/31/19
Pharmaceuticals	Unapproved drugs Misbranding	Prescription Dispensing Laboratories, Inc. dba PD Labs	7/30/19
Pharmaceuticals	Adulteration Unapproved drugs Misbranding	Promise Pharmacy, LLC	7/29/19
Pharmaceuticals	CGMP Adulteration	Results RNA, LLC	7/29/19
Pharmaceuticals	Adulteration Misbranding Unapproved drugs	Curaleaf, Inc.	7/22/19
Pharmaceuticals	CGMP	CTX Lifesciences Private Ltd.	7/12/19
Pharmaceuticals	Adulteration CGMP Data Integrity	Strides Pharma Science Limited	7/1/19
Pharmaceuticals	Misbranding Listing obligations	American Sales Company Inc.	7/11/19
Pharmaceuticals	Adulteration Misbranding Labeling	Farmville Discount Drug, Inc. DBA Best Value Drug	7/9/19
Pharmaceuticals	Adulteration CGMP Data Integrity	Indoco Remedies Limited	7/9/19
Pharmaceuticals	Adulteration CGMP	High Chemical Company	7/2/19
Pharmaceuticals	Adulteration CGMP	AllerQuest LLC	6/24/19
Pharmaceuticals	Adulteration CGMP	Aurobindo Pharma Limited	6/20/19
Medical Devices	Adulteration QSR	Clinicon Corp	6/20/19
Pharmaceuticals	Adulteration	Ideal Specialty Apothecary, Inc. dba Ideal Pharmacy	6/17/19
Pharmaceuticals	Adulteration CGMP	Akorn Inc.	6/13/19
Pharmaceuticals	Adulteration CGMP	Rxhomeo Private Limited	6/13/19

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Pharmaceuticals	Adulteration CGMP	SnugZ USA, Inc.	6/12/19
Pharmaceuticals	Adulteration CGMP	Asclemed USA Inc. dba Enovachem	6/11/19
Pharmaceuticals	Unapproved drugs	Cali Botanicals, LLC	6/11/19
Pharmaceuticals	CGMP Adulteration Data integrity	Deb USA Inc.	6/11/19
Pharmaceuticals	Unapproved drugs Misbranding CGMP	Perfect Choice Trading, Inc. & Nutricos Ceuticals, Inc.	6/11/19
Pharmaceuticals	Adulteration CGMP Misbranding	Xi'an Livingbond Nonwoven Products Corp., Ltd.	6/10/19
Pharmaceuticals	Misbranding Unapproved drugs	Earthworks Health	6/7/19
Pharmaceuticals	Adulterated Unapproved drugs Misbranded	Imprimis NJOF, LLC	6/7/19
Pharmaceuticals	Adulteration CGMP	US Pharmaceuticals Inc.	6/6/19
Pharmaceuticals	CGMP Unapproved drugs	Advanced Botanical Consulting & Testing Inc dba ABC Testing	6/4/19
Pharmaceuticals	Unapproved drugs	B & B Pharmaceuticals, Inc.	6/4/19
Pharmaceuticals	Adulteration CGMP Misbranding	Spectrum Laboratory Products	6/4/19
Pharmaceuticals	CGMP Data Integrity Misbranding Unapproved drugs	Glint Cosmetics Pvt Ltd	5/31/19
Pharmaceuticals	Adulteration CGMP Unapproved drugs	Ingenue Care	5/31/19
Medical Devices	Adulteration QSR	International Hospital Products, Inc.	5/29/19
Pharmaceuticals	Adulteration CGMP	Vida International, Inc.	5/29/19
Pharmaceuticals	Adulteration CGMP Misbranding	Izeen Pharma Inc	5/16/19
Pharmaceuticals	Misbranding Unapproved drugs	KratomNC	5/16/19
Pharmaceuticals	Adulteration CGMP Unapproved drugs	McDaniel Life-Line LLC	5/16/19
Pharmaceuticals	Misbranding Unapproved Drugs	ActiveHerb Technology, Inc	5/15/19
Pharmaceuticals	Adulteration CGMP Unapproved Drugs	Tropical Seas, Inc.	5/15/19
Pharmaceuticals	Adulteration CGMP Misbranding	Kingston Pharma LLC	5/14/19

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Medical Devices	Misbranding	21st Century Scientific Inc.	5/13/19
Medical Devices	Adulteration QSR	Orchid Orthopedic Solutions, LLC	5/13/19
Medical Devices	QSR	Rechargeable Power Energy North America LLC	5/9/19
Pharmaceuticals	Adulteration Misbranding	Rocky Mountain Pharmacy Inc.	5/9/19
Medical Devices	Misbranding QSR	Zeller Power Products, LLC	5/9/19
Pharmaceuticals	Adulteration CGMP	AMMD Labs, LLC	5/7/19
Pharmaceuticals	Adulteration CGMP	Petra Hygienic Systems Int Ltd	5/7/19
Pharmaceuticals	Adulteration CGMP	Centurion Laboratories Private Limited	5/4/19
Pharmaceuticals	Adulteration CGMP	Bershtel Enterprises LLC dba WePackItAll	5/2/19
Pharmaceuticals	Adulteration CGMP	Fill It Pack It Inc	5/2/19
Pharmaceuticals	Adulteration CGMP Misbranding Unapproved drug	Kadesh International	5/2/19
Pharmaceuticals	Adulteration CGMP	U.S. Continental Marketing, Inc.	5/2/19
Pharmaceuticals	Unapproved drugs Misbranding	Golean Detox US	4/29/19
Pharmaceuticals	CGMP Adulteration	Laboratoires Clarins	4/23/19
Pharmaceuticals	Adulteration CGMP Misbranding	Ecometics, Inc.	4/16/19
Medical Devices	Premarket Approval (PMA) Misbranding Adulteration Investigational Device Exemption (IDE)	Innovative Sterilization Technologies LLC	3/20/19
Pharmaceuticals	Unapproved drugs Misbranding	Aidaccess.org	3/8/19
Pharmaceuticals	Unapproved drugs Misbranding	CanaRx Services Inc.	2/26/19