

Government of Canada

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> Reports and Publications - Drugs and Health Products > Compliance and Enforcement

Inspection tracker: Drug manufacturing establishments

As part of Health Canada's ongoing commitment to openness and transparency, the Department is publishing information regarding emerging issues identified through our drug inspection program.

This tracker provides a snapshot of the potential health and safety issues Health Canada is tracking with companies that fabricate, package/label, test, wholesale, distribute or import drugs for sale in Canada. The information in the chart will expand to eventually include details about affected Canadian companies and products.

How the inspection tracker works

- Health Canada responds to potential risks as soon as we hear about them whether from our own inspections, the companies themselves, adverse reaction reports or from our regulatory partners.
- The tracker highlights actions Health Canada is taking such as: requests for voluntary quarantine, stop sales, import restrictions, or product recalls. It also indicates those circumstances where no action has been warranted.
- Even if a company is listed on the tracker, it doesn't necessarily mean there is an immediate risk to the health of Canadians. It means Health

Canada is looking into a potential issue.

- Health Canada will continue to take action to manage risks identified to the health of Canadians using the most appropriate level of intervention, proportional to the risk to health.
- This tracker currently doesn't list specific drugs and health products affected but links to Recalls and Safety Alerts if a risk has been linked to specific products on the Canadian market.
- This tracker is updated regularly.
- Once an item is listed in the closed section, it indicates that there is no further action being taken by Health Canada at this time and there will be no more updates regarding this item.
- Last update: April 17, 2023

Open items

Establishment	Status of issue	Source of information under review	Primary reason for action
Felix Generics Private Limited Plot No. M-24, 25, 26 & 27, Special Economic Zone, Phase II, Pithampur, Dhar, Madhya Pradesh, 454775, India NEW	 Canadian importer(s) contacted by Health Canada for information Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) 	Regulatory Partner(s)	General GMP observations

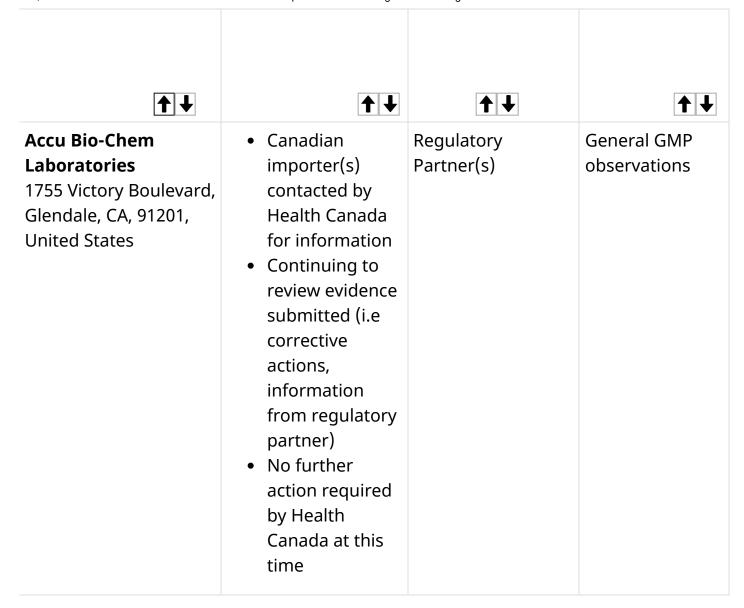
Establishment	Status of issue	Source of information under review	Primary reason for action
Kyowa Hakko Bio Co., Ltd. 1-1 Kyowa-cho, Hofu-shi, Yamaguchi, Yamaguchi, 747-8522, Japan NEW	 Canadian importer(s) contacted by Health Canada for information Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) 	Regulatory Partner(s)	General GMP observations
Lupin Limited Unit 1 Unit 1, 198-202 New Ind Area No 2, Mandideep Madhya Pradesh, India	 Canadian importer(s) contacted by Health Canada for information Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) 	Regulatory Partner(s)	General GMP observations

Establishment	Status of issue	Source of information under review	Primary reason for action	
Megafine Pharma (P) Ltd. Plot No. 31 to 35 & 48 to 51, 5, 26 & K/201, Lakhmapur, Dindori (Taluka), Nashik (District), Maharashtra, 422202, India	 Canadian importer(s) contacted by Health Canada for information Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) No further action required by Health Canada at this time 	Regulatory Partner(s)	General GMP observations	
Nephron Pharmaceuticals Corporation 4500 12th Street Extension, West Columbia, SC, 29172, United States	 Canadian importer(s) contacted by Health Canada for information Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) No further action required by Health Canada at this time 	Regulatory Partner(s)	General GMP observations	

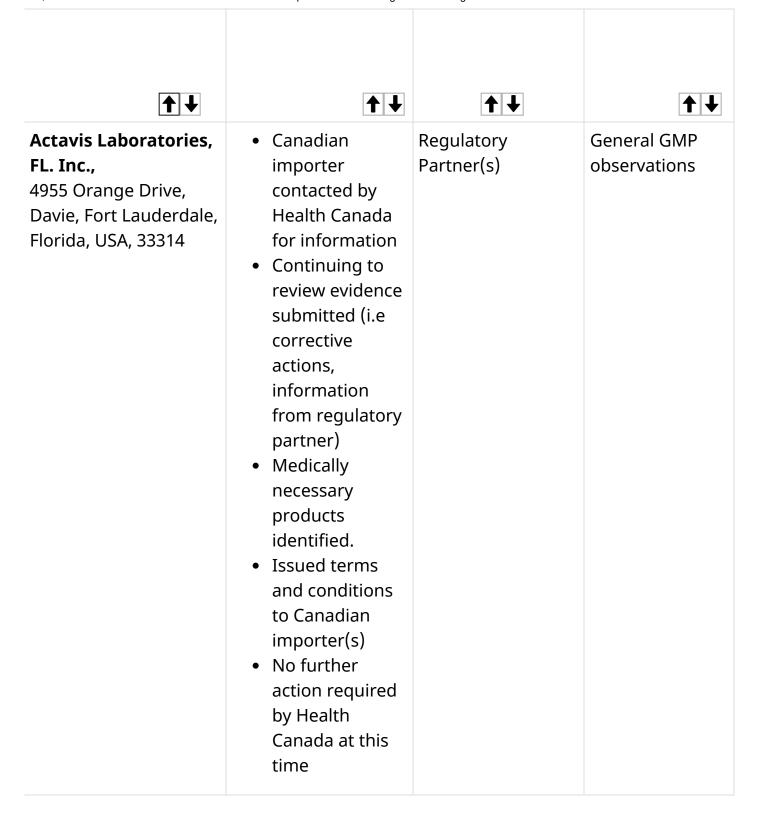
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	Show	10	~	entries

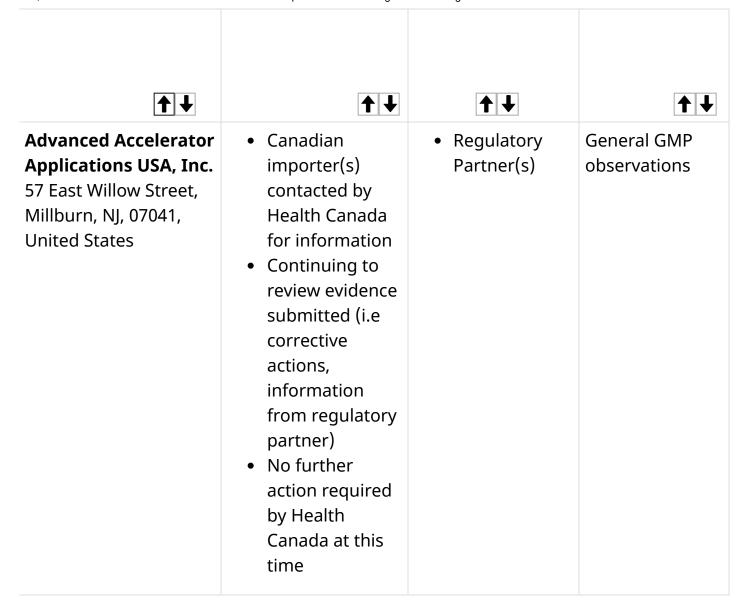
Closed items

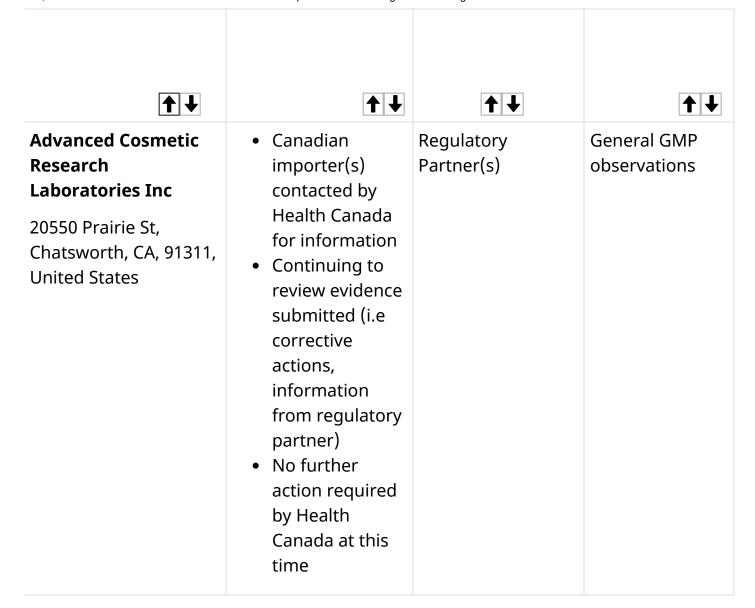
Establishment 🚹 🖶	Status of issue 1	Source of information under review	Primary reason for action
Abraxis Bioscience LLC 620 N. 51st Avenue, Phoenix, AZ, 85043, United States	 Canadian importer(s) contacted by Health Canada for information Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) No further action required by Health Canada at this time 	Regulatory Partner(s)	General GMP observations

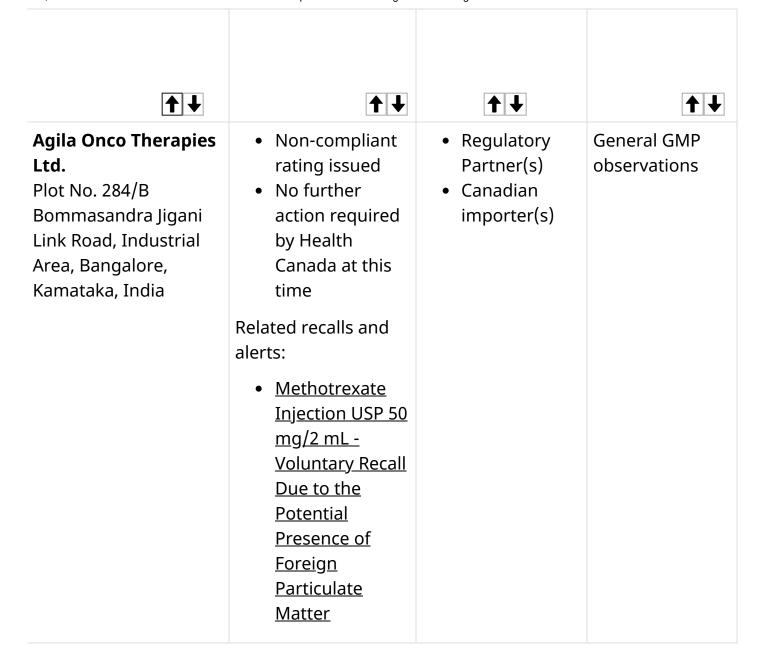


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Acharya Chemicals W41 &W42, MIDC Industrial estate - Morivali Village, 421501 AMBARNATH (W) (Dist Thane), 42150, India	 Canadian importer contacted by Health Canada for information Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) No further action required by Health Canada at this time 	Regulatory Partner(s)	General GMP observations

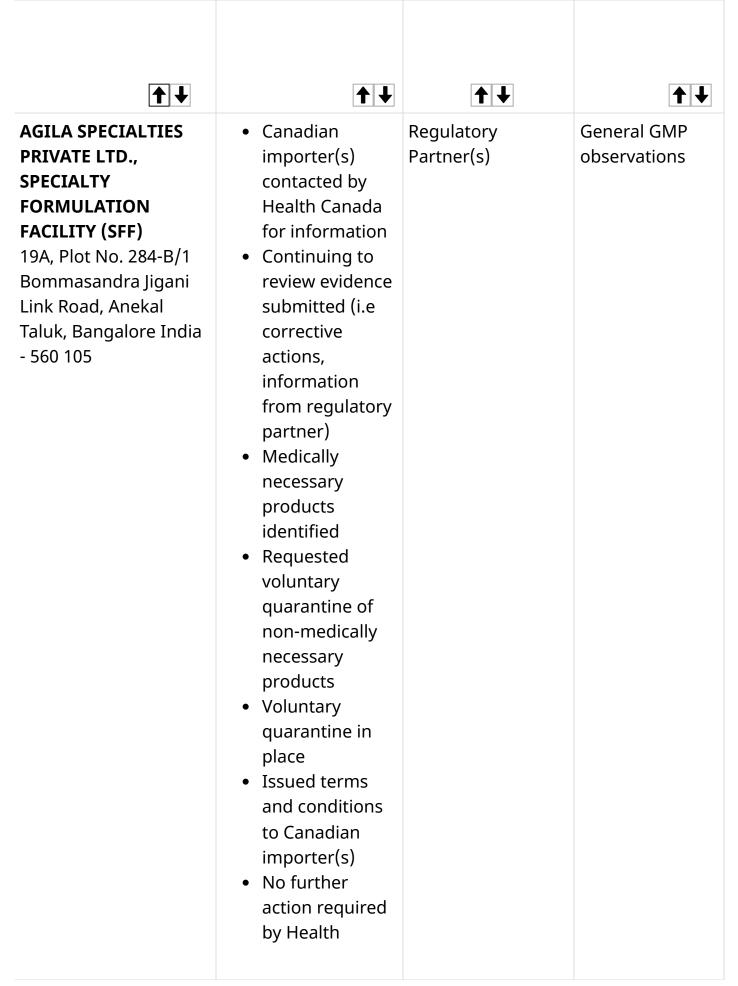








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AGILA SPECIALTIES PRIVATE LTD. Opp II M, Bilekahalli, Bannerghatta Road, Bangalore, Karnataka, India - 560 076	 Canadian importer(s) contacted by Health Canada for information No critical risks identified to date No further action required by Health Canada at this time 	Regulatory Partner(s)	General GMP observations



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↑		Canada at this time						1
Akorn Inc. 1222 West Grand Av Decatur, IL USA, 62522-1412	re	Canadian		Regul	latory er(s)	General GMP observations		
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Date modified:

2023-04-17