

Government of Canada

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- **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: February 15, 2023

Open items

		Source of	Primary
		information	reason for
Establishment	Status of issue	under review	action

Establishment	Status of issue	Source of information under review	Primary reason for action
Advanced Cosmetic Research Laboratories Inc 20550 Prairie St, Chatsworth, CA, 91311, 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
Cangene BioPharma LLC dba Emergent BioSolutions 1111 South Paca Street, Camden Industrial Park, Baltimore, MD, 21230, 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

Establishment	Status of issue	Source of information under review	Primary reason for action
Centrient Pharmaceuticals India Private Limited Bhai Mohan Singh Nagar, Toansa, Distt.SBS, Nagar (Nawanshahr), Punjab, 144 533, 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
Glenmark Pharmaceuticals Limited Plot No. S-7, Colvale Industrial Estate, Colvale, Bardez, Goa, 403513, 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

	Inspection tracker. Drug manufacturing		
Establishment	Status of issue	Source of information under review	Primary reason for action
Glenmark Pharmaceuticals Limited, Unit I Village Kishanpura, Baddi Nalagarh Road, Baddi, Solan, Himachal 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
Jurox Pty Ltd. 85 Gardiner Street, Rutherford, New South Wales, 2320, Australia	 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

Establishment	Status of issue	Source of information under review	Primary reason for action
Lupin Limited Unit 1 Unit 1, 198-202 New Ind Area No 2, Mandideep Madhya Pradesh, India	198-202 New Ind o 2, Mandideep importer(s) contacted by Health Canada for		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) 	Regulatory Partner(s)	General GMP observations
Sun Pharmaceutical Industries Limited Halol Baroda Highway, Halol, Gujarat, 389 350, 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
Trifarma S.P.A Via Pavese 2, Rozzano, N/A, 20089, Italy	 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

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Filter items	Showing 1 to 10 of 193 entrie			

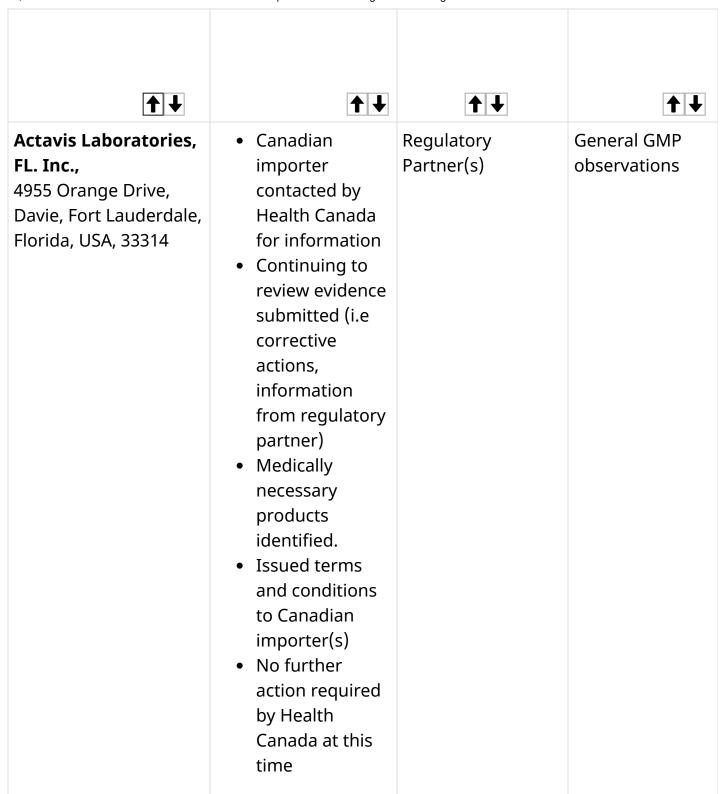
Closed items

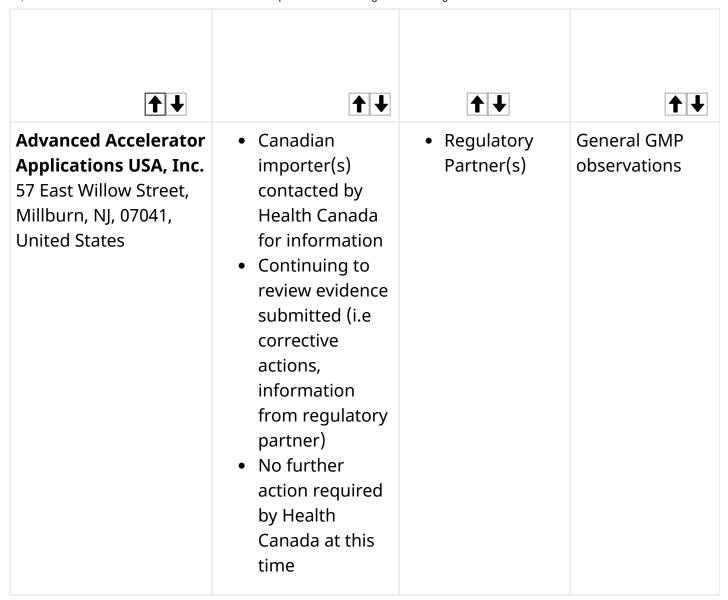
		Source of information	
		under	Primary reason
Establishment ↑ ↓	Status of issue ↑ ↓	review ↑ ↓	for action 🕇 🖶

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↑ ↓ Abraxis Bioscience	• Canadian	↑ ↓ Regulatory	↑ ↓ General GMP
LLC 620 N. 51st Avenue, Phoenix, AZ, 85043, United States	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	Partner(s)	observations

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Accu Bio-Chem Laboratories 1755 Victory Boulevard, Glendale, CA, 91201, 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

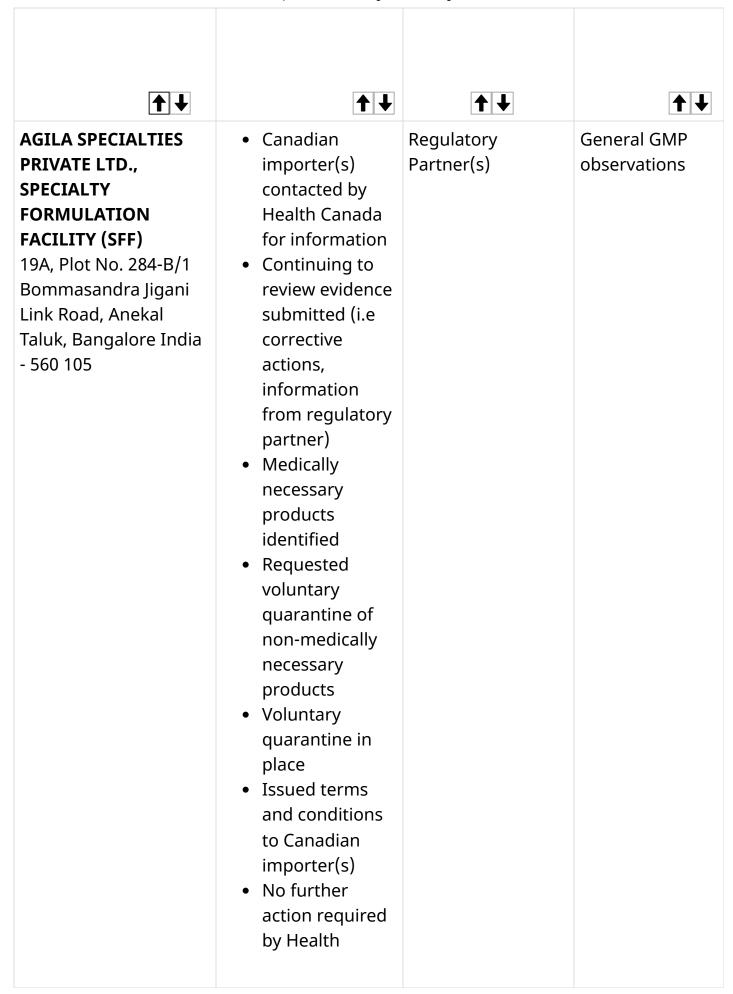
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Acharya Chemicals W41 &W42, MIDC Industrial estate - Morivali Village, 421501 AMBARNATH (W) (Dist Thane), 42150, India	 Canadian importer contacted by Health Canada for information Continuing to review evidence submitted (i.e corrective actions, information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





Agila Onco Therapies Ltd. Plot No. 284/B Bommasandra Jigani Link Road, Industrial Area, Bangalore, Kamataka, India Related recalls and alerts: Methotrexate Injection USP 50 mg/2 mL - Voluntary Recall Due to the Potential Partner(s) Canadian importer(s) Canadian importer(s) Methotrexate Injection USP 50 mg/2 mL - Voluntary Recall Due to the Potential				
Plot No. 284/B Bommasandra Jigani Link Road, Industrial Area, Bangalore, Kamataka, India Related recalls and alerts: • Methotrexate Injection USP 50 mg/2 mL - Voluntary Recall Due to the Partner(s) • Canadian importer(s) • Canadian importer(s)	1	1	1	1
Foreign Particulate Matter	Ltd. Plot No. 284/B Bommasandra Jigani Link Road, Industrial Area, Bangalore,	rating issued No further action required by Health Canada at this time Related recalls and alerts: Methotrexate Injection USP 50 mg/2 mL - Voluntary Recall Due to the Potential Presence of Foreign Particulate	Partner(s) • Canadian	

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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



inspection tracker. Drug manufacturing establishments - Canada.ca					
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Akorn Inc. 1222 West Grand Ave Decatur, IL USA, 62522-1412	 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		



Date modified:

2023-02-16