

Government of Canada

Gouvernement du Canada

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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: January 3, 2023

Open items

Establishment	Status of issue	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) 	Regulatory Partner(s)	General GMP observations

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Establishment	tablishment Status of issue		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) 	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) 	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) 	Regulatory Partner(s)	General GMP observations
CTX Lifesciences Private Ltd. Block No. 251-252 Sachin-Magdalla Road, GIDC, Sachin, Surat 394230 Gujarat, 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
Glenmark Pharmaceuticals Limited Plot No. S-7, Colvale Industrial Estate, Colvale, Bardez, Goa, 403513, 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
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

Establishment	Status of issue	Source of information under review	Primary reason for action	
Jost Chemicals Co. 8150 Lackland Rd. Saint Louis, Missouri, US	 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	
Jurox Pty Ltd. 85 Gardiner Street, Rutherford, New South Wales, 2320, Australia 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	Source of information information in the second sec		Primary reason for action
Kopran Research Laboratories Limited K-4/4 Additional MIDC, At&Post Birwadi, Raigad District, Mahad, Maharashtra, India, 402302	 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
Lupin Limited T-142, M.I.D.C. Tarapur, Via Boisar, Tal Palghar, Maharashtra, 401 506, 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
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
Nephron Pharmaceuticals Corporation 4500 12th Street Extension, West Columbia, SC, 29172, United States 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
Sun Pharmaceutical Industries Limited Halol Baroda Highway, Halol, Gujarat, 389 350, 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
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

Establishment	Status of issue	Source of information under review	Primary reason for action
Zhejiang Tianyu Pharmaceutical Co. Limited Jiangkou Development Zone, Huangyan District, Taizhou, Zhejiang, 318020, China	 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

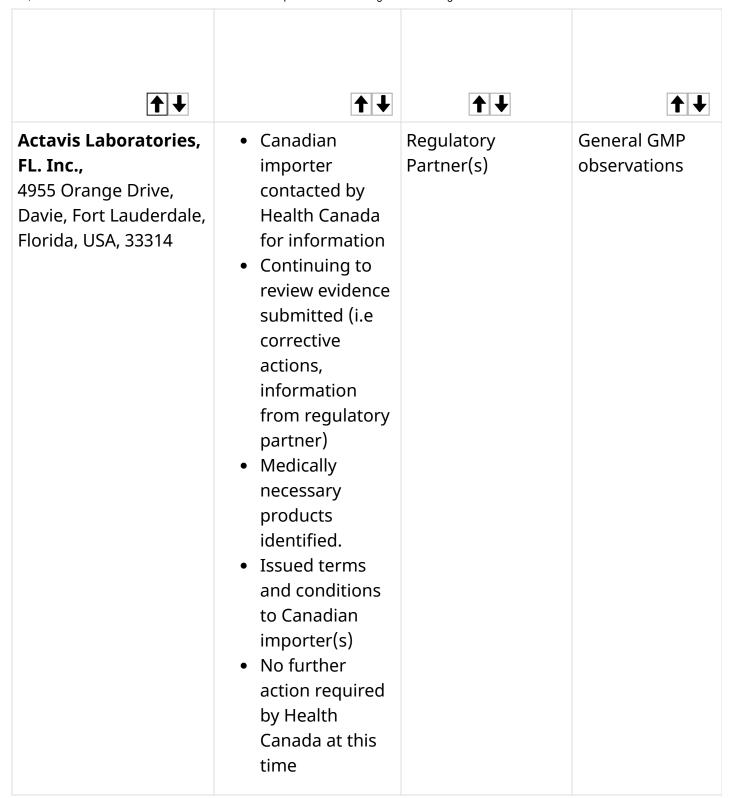
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Closed items

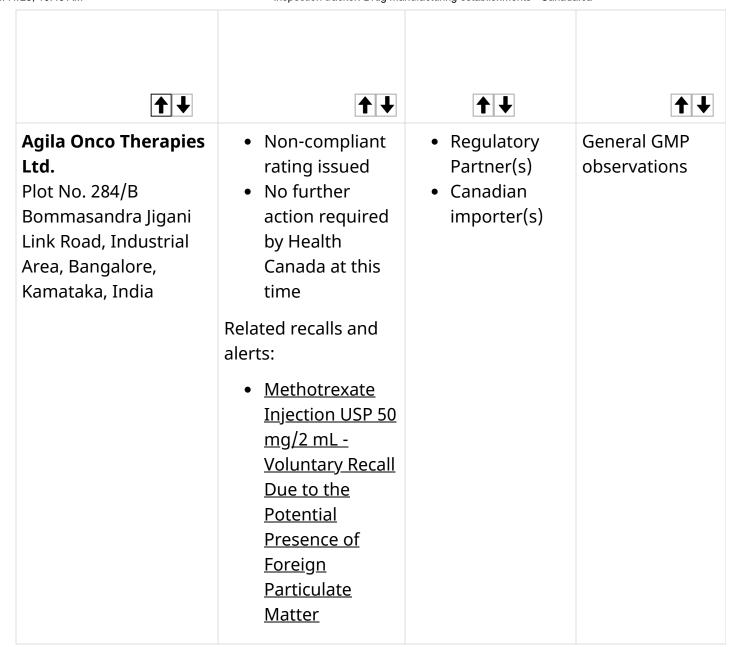
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Accu Bio-Chem Laboratories 1755 Victory Boulevard, Glendale, CA, 91201, United States	 Canadian importer(s) contacted by Health Canada for information Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner) No further action required by Health Canada at this time 	Regulatory Partner(s)	General GMP observations

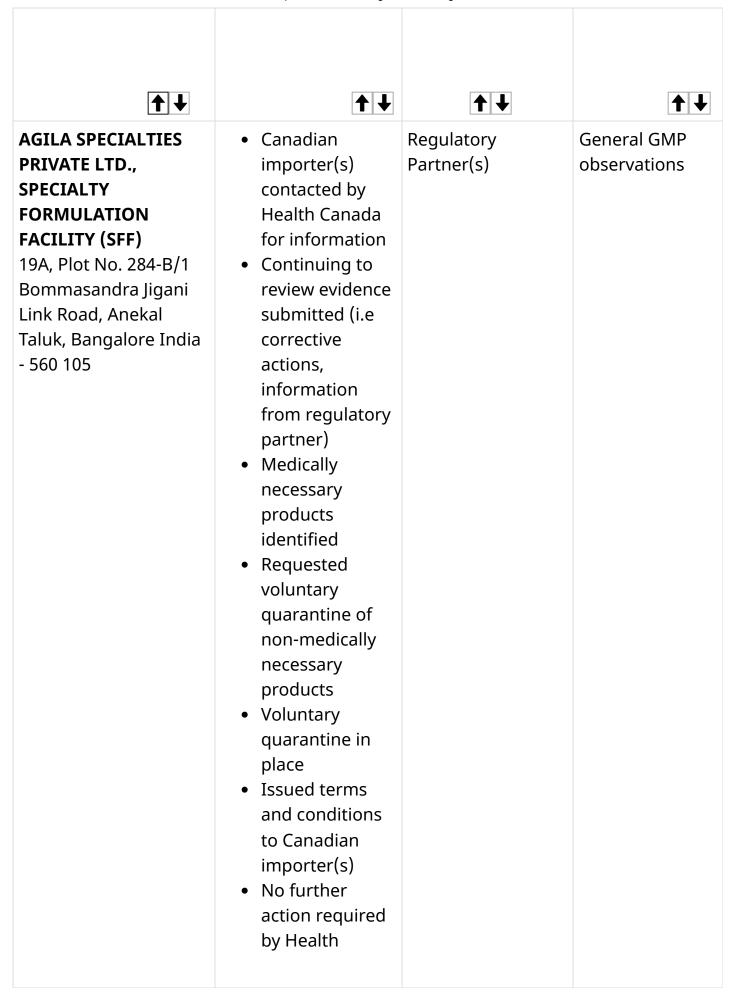
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Acharya Chemicals W41 &W42, MIDC Industrial estate - Morivali Village, 421501 AMBARNATH (W) (Dist Thane), 42150, India	 Canadian importer contacted by Health Canada for information Continuing to review evidence submitted (i.e corrective actions, information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



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Advanced Accelerator Applications USA, Inc. 57 East Willow Street, Millburn, NJ, 07041, 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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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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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

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Akorn Inc. 72 Veronica Ave, Somerset NJ, 08873, USA	 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:

2023-01-03