

# Government of Canada

# Gouvernement du Canada

<u>Canada.ca</u> ➤ <u>Departments and agencies</u> ➤ <u>Health Canada</u> ➤ <u>Drugs and health products</u>

➤ 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 <u>Recalls and Safety Alerts</u> 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 <u>closed section</u>, 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: September 5, 2024

#### **Open items**

Establishment	Status of issue	Source of information under review	Primary reason for action
Aspen SA Sterile Operations 8b Gibaud Road, Port Elizabeth, Eastern Cape, South Africa New	<ul> <li>Canadian importer(s) contacted by Health Canada for information</li> <li>Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner</li> </ul>	Regulatory Partner(s)	General GMP observations

Establishment	Status of issue	Source of information under review	Primary reason for action
Eugia Pharma Specialities Limited (Unit III) Plot No 4, 34 to 48, EPIP, TSIIC, IDA-Pashamylaram, Patancheru (Mandal), Sangareddy, Hyderabad, India	<ul> <li>Canadian importer(s) contacted by Health Canada for information</li> <li>Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner</li> <li>No further action required by Health Canada at this time</li> </ul>	Regulatory Partner(s)	General GMP observations
Genzyme Corporation 8, 45, 51, 68, 74, 76 New York Avenue, Framingham, MA, 01701- 9322, United States New	<ul> <li>Canadian importer(s) contacted by Health Canada for information</li> <li>Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner</li> <li>No further action required by Health Canada at this time</li> </ul>	Regulatory Partner(s)	General GMP observations

Establishment	Status of issue	Source of information under review	Primary reason for action		
Global Calcium Private Limited 125, 126 SIPCOT Industrial Complex, Hosur, Tamil Nadu, 635 126, India New	<ul> <li>Canadian importer(s) contacted by Health Canada for information</li> <li>Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner</li> <li>No further action required by Health Canada at this time</li> </ul>	Regulatory Partner(s)	General GMP observations		
Indoco Remedies Limited Plants II and III Goa L-32, 33, 34, Verna Industrial Area, India New	<ul> <li>Canadian importer(s) contacted by Health Canada for information</li> <li>Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner</li> </ul>	Regulatory Partner(s)	General GMP observations		

Establishment	Status of issue	Source of information under review	Primary reason for action
Jagsonpal Pharmaceuticals B-1124, RIICO Industrial Area Phase III, Bhiwadi, Alwar, Rajasthan, India New	<ul> <li>Canadian importer(s) contacted by Health Canada for information</li> <li>Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner</li> </ul>	Partner(s)	
Mylan Laboratories Limited (a Viatris company) Plot No. 11, 12 & 13, Indore SEZ Pharma Zone, Phase-II, Sector-III, Pithampur, Dhar, Madhya Pradesh, India New	<ul> <li>Canadian importer(s) contacted by Health Canada for information</li> <li>Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner</li> </ul>	Regulatory partner(s)	General GMP observations

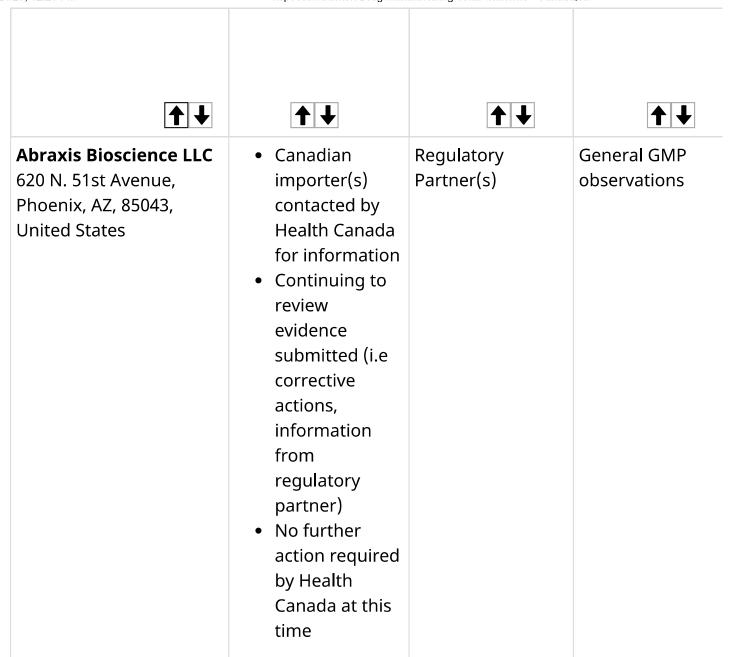
Establishment	Status of issue	Source of information under review	Primary reason for action
Nectar Lifesciences Limited Village Bhatolikalan - Adjoining Jharmajri E.P.I.P., P.O. Barotiwala, Tehsil Baddi District Solan, Himachal Pradesh, 174 103, India New	<ul> <li>Canadian importer(s) contacted by Health Canada for information</li> <li>Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner</li> </ul>	Regulatory Partner(s)	General GMP observations
Tyche Industries 6 - 223 Sarpavaram (V), Kakinada, Andhra Pradesh India New	<ul> <li>Canadian importer(s) contacted by Health Canada for information</li> <li>Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner</li> </ul>	Regulatory Partner(s)	General GMP observations

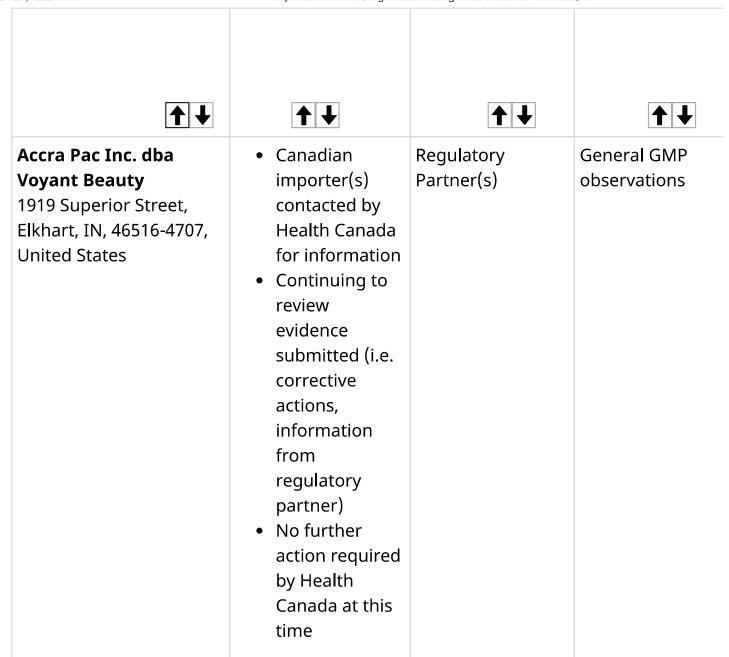
Establishment	Status of issue	Source of information under review	Primary reason for action
Yung Shin Pharma 27 Kung Chiu Road, Tachia, 43769, Taiwan New	<ul> <li>Canadian importer(s) contacted by Health Canada for information</li> <li>Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner</li> </ul>	Regulatory Partner(s)	General GMP observations

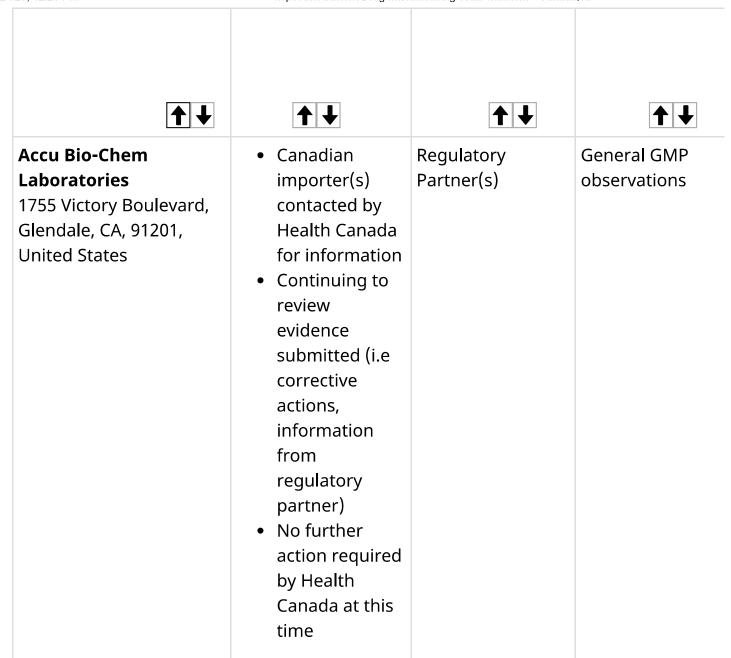
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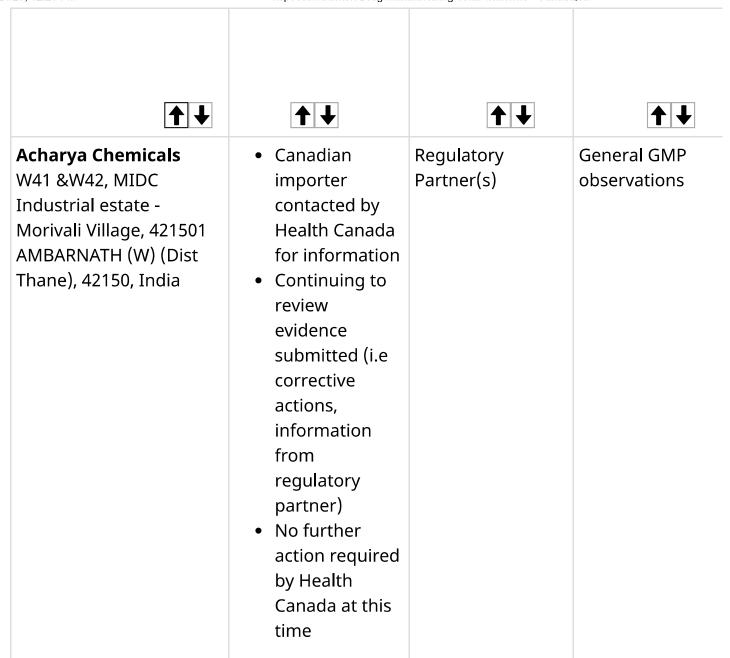
#### **Closed items**

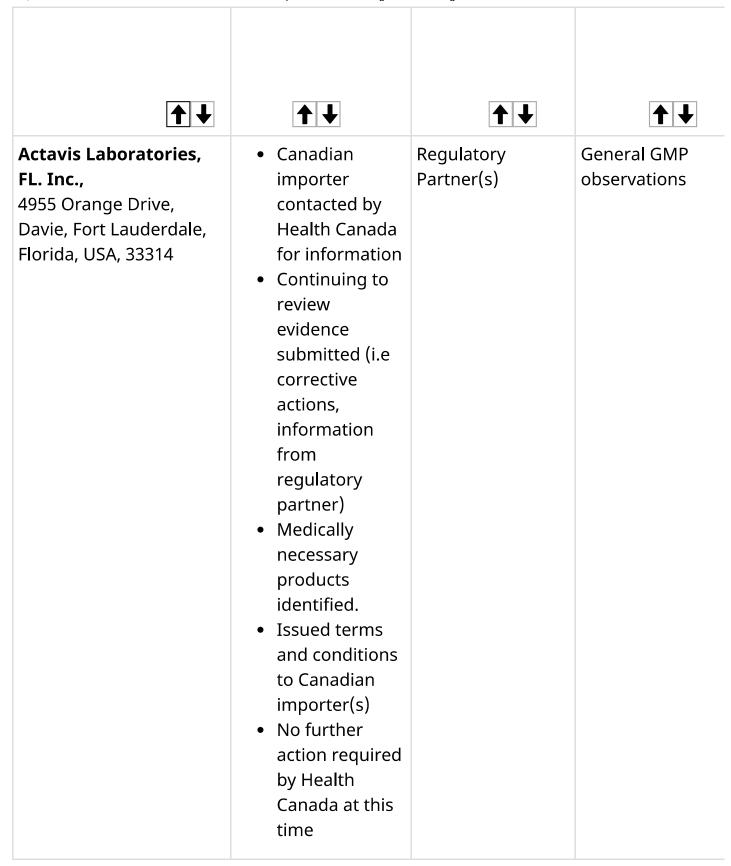
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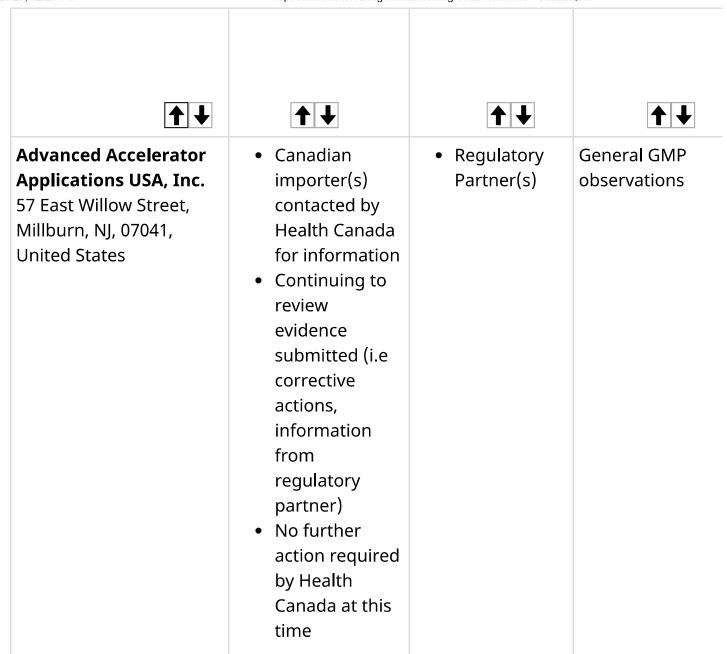


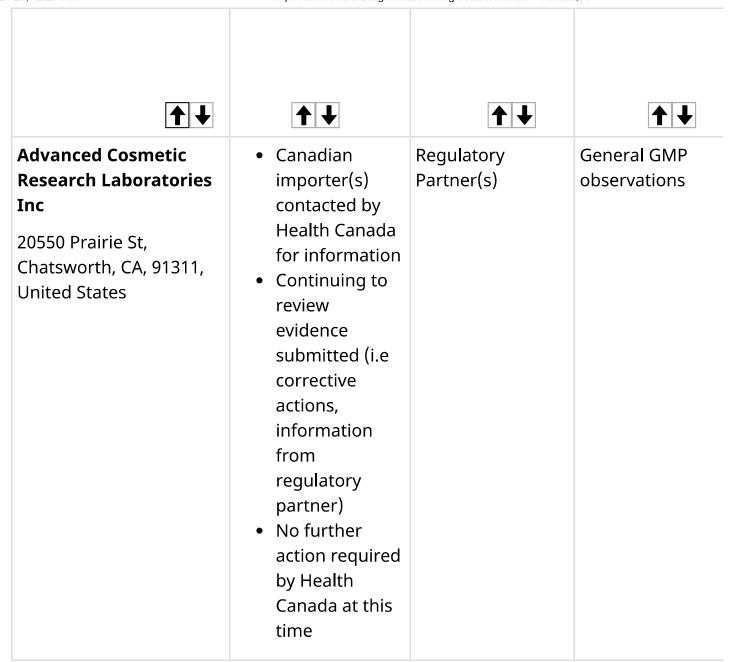


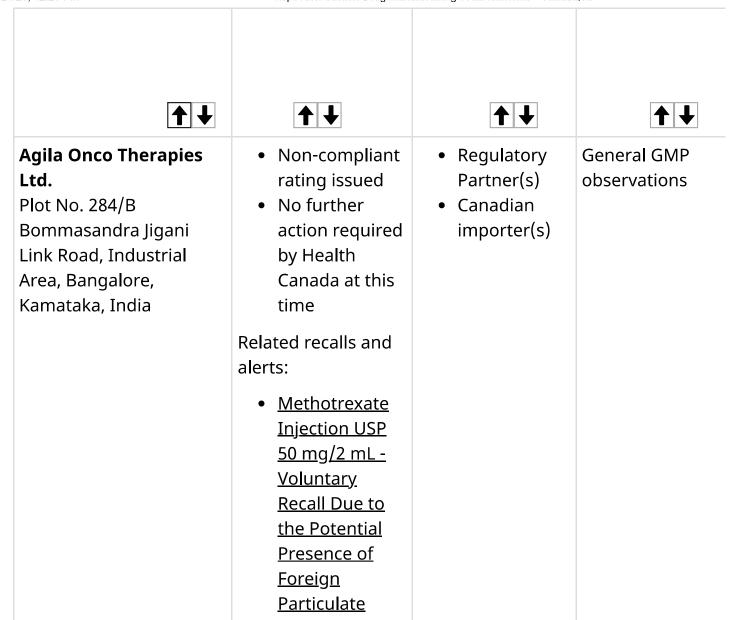












<u>Matter</u>

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









# AGILA SPECIALTIES PRIVATE LTD., SPECIALTY FORMULATION FACILITY (SFF)

19A, Plot No. 284-B/1 Bommasandra Jigani Link Road, Anekal Taluk, Bangalore India - 560 105

- Canadian importer(s) contacted by Health Canada for information
- Continuing to review evidence submitted (i.e corrective actions, information from regulatory partner)
- Medically necessary products identified
- Requested voluntary quarantine of non-medically necessary products
- Voluntary quarantine in place
- Issued terms and conditions to Canadian importer(s)

# Regulatory Partner(s)

General GMP observations



#### Date modified:

2025-03-04