

# 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: October 4, 2023

## **Open items**

Establishment	Status of issue	Source of information under review	Primary reason for action
Baxter Pharmaceuticals India Pvt. Ltd. Village Vasana Chacharwadi, Taluka Sanand, Ahmedabad, 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> </ul>	Regulatory Partner(s)	General GMP observations

Establishment	Status of issue	Source of information under review	Primary reason for action
Pharmaceuticals Ltd. Vision Unit, 126 Kathaldia Auchpara, Tongi, Gazipur, 1711, Bangladesh	<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
Centaur Pharmaceuticals Private Ltd Plot No.4, International Biotech Park, Phase-II, Hinjewadi, Pune, Maharashtra, 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> </ul>	Regulatory Partner(s)	General GMP observations

Establishment  Centaur Pharmaceuticals Pvt Ltd Plot No. 75, 76 and 76/1 Chikhloli MIDC, Ambernath (West), Dist. Thane, Maharashtra, 421501, India	<ul> <li>Status of issue</li> <li>Canadian importer(s) contacted by Health Canada for information</li> <li>Continuing to review evidence submitted (i.e corrective actions,</li> </ul>	Source of information under review Regulatory Partner(s)	Primary reason for action  General GMP observations
	<ul> <li>information from regulatory partner)</li> <li>No further action required by Health Canada at this time</li> </ul>		
K.C. Pharmaceuticals Inc. 3215 Producer Way, Pomona, CA, USA 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

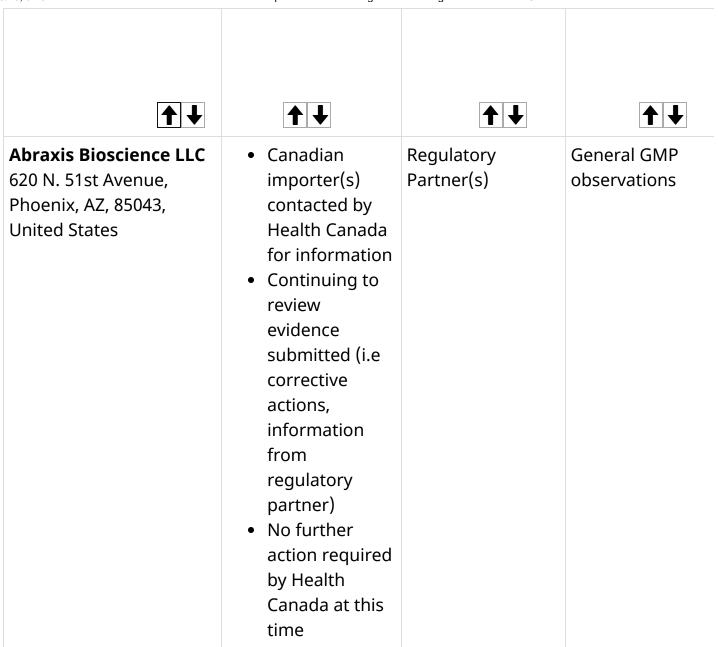
Establishment	Status of issue	Source of information under review	Primary reason for action
Medgel Private Limited Special Economic Zone, Phase-II, Sector-III, Pithampur, Dist. Dhar (M.P.), India	<ul> <li>Canadian importer(s) contacted by Health Canada for information</li> <li>Continuing to review evidence submitted (i.e. corrective actions, information from regulatory partner)</li> </ul>	Regulatory Partner(s)	General GMP observations
Neilmed Pharmaceuticals Inc 601 Aviation Blvd, Santa Rosa, CA, 95403, United States	<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

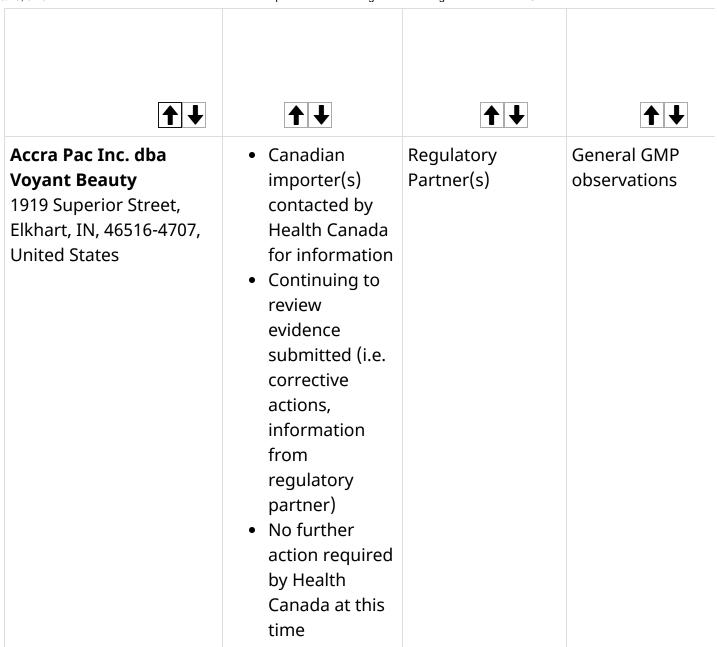
Establishment	Status of issue	Source of information under review	Primary reason for action
Spectrum Chemical Mfg Corp. 755 and 769 Jersey Avenue, New Brunswick, NJ, 08901, United States	<ul> <li>Canadian importer(s) contacted by Health Canada for information</li> <li>Continuing to review evidence submitted (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

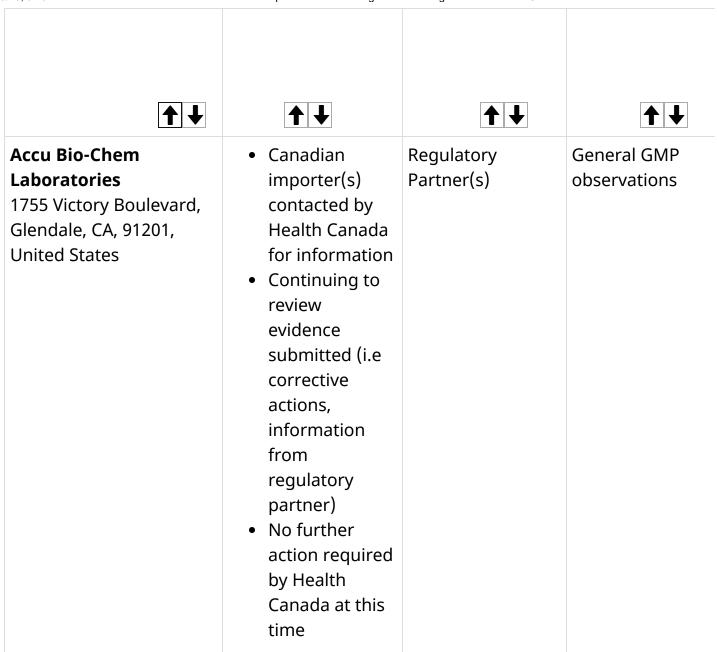
Filter items	Showi	ng 1	to	10 of 215 entries
'	 Show	10	~	entries

## **Closed items**

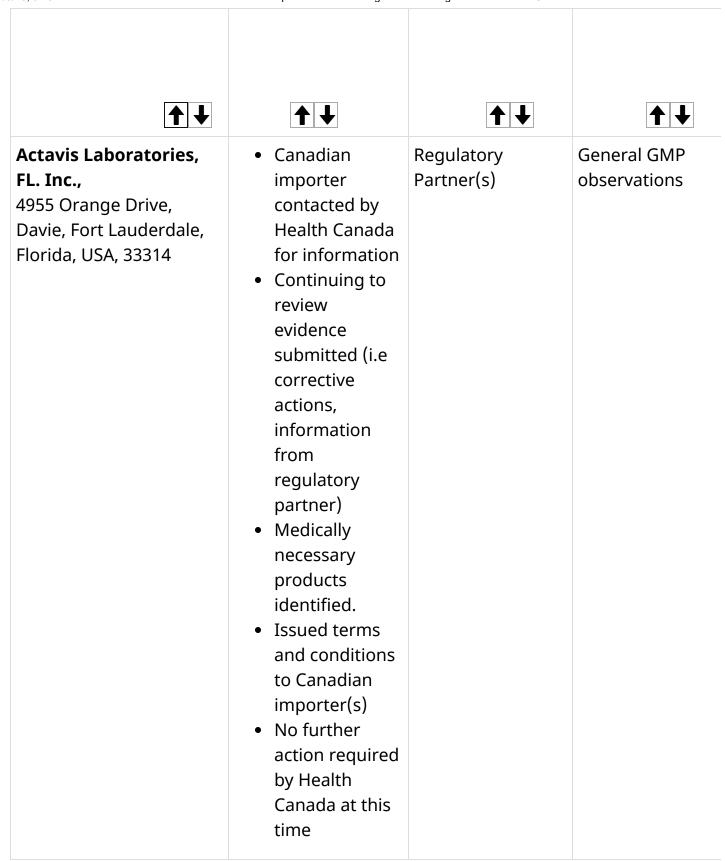
		Source of	
		information	Primary
	Status of	under	reason for
Establishment <b>↑ ↓</b>	issue ↑↓	review ↑ ↓	action <b>↑ ↓</b>

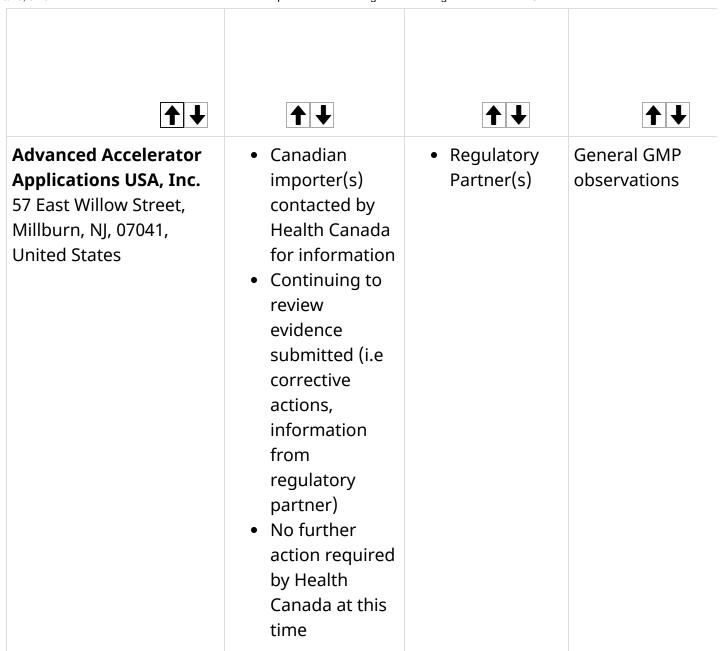




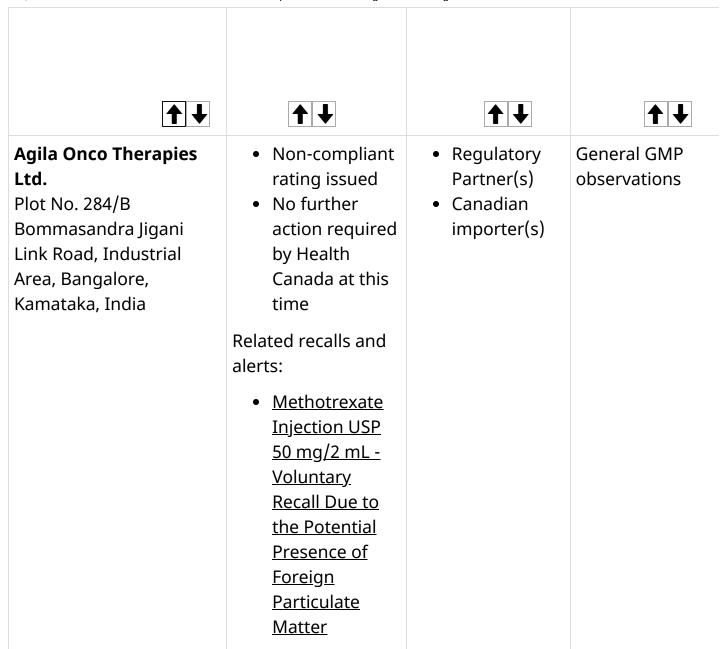


173720, 3.13 AW	moposion racker. Brag mane	Tactaring Catabilaninents - Canada	
<b>1</b>	<b>↑</b>	1	1
Acharya Chemicals W41 &W42, MIDC Industrial estate - Morivali Village, 421501 AMBARNATH (W) (Dist Thane), 42150, India	<ul> <li>Canadian importer contacted by Health Canada for information</li> <li>Continuing 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



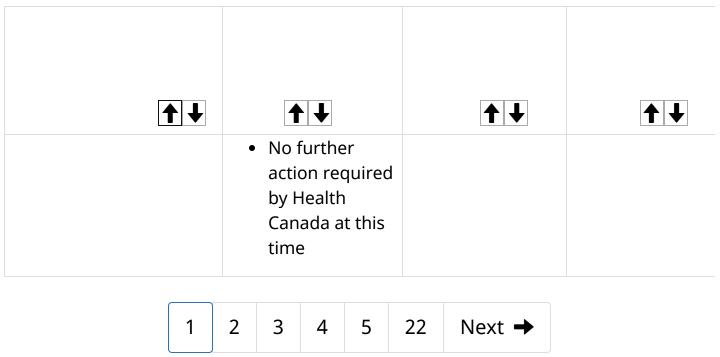


1/9/23, 9.19 AW	inspection tracker. Drug mant	nacturing establishments - Canada	ı.ua
1	<b>↑</b>	1	1
Advanced Cosmetic Research Laboratories Inc 20550 Prairie St, Chatsworth, CA, 91311, United States	<ul> <li>Canadian importer(s) contacted by Health Canada for information</li> <li>Continuing to review 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



5/25, 5.18 AWI		Tractuming establishments - Canada	
1	<b>↑</b>	1	<b>↑</b>
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





#### Date modified:

2023-11-03