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# Inspection tracker: Drug manufacturing establishments

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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 & 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: **November 12, 2021**

## Open Items

Establishment	Status of Issue	Source of Information under Review	Primary Reason for Action
<b>Cipla Limited</b> Unit VIII, S-103 To S-105, S-107 To S-112, L-147, L-147/1 & L-147/3	<ul style="list-style-type: none"> <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

<b>Establishment</b>	<b>Status of Issue</b>	<b>Source of Information under Review</b>	<b>Primary Reason for Action</b>
<p><b>Cosmax USA</b> 30701 Carter Street, Solon, OH, 44139, United States</p> <p><b>NEW</b></p>	<ul style="list-style-type: none"> <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
<p><b>CTX Lifesciences Private Ltd.</b> Block No. 251-252 Sachin-Magdalla Road, GIDC, Sachin, Surat 394230 Gujarat, India</p>	<ul style="list-style-type: none"> <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

<b>Establishment</b>	<b>Status of Issue</b>	<b>Source of Information under Review</b>	<b>Primary Reason for Action</b>
<p><b>Emergent Manufacturing Operations Baltimore, LLC</b> 5901 East Lombard Street, Baltimore, MD, 21224, United States</p>	<ul style="list-style-type: none"> <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>• Issued terms and conditions to Canadian importer(s)</li> <li>• Health Canada on-site inspection [2021-10-25]</li> </ul>	Regulatory Partner(s)	General GMP observations
<p><b>Imaretcioğlu İlac Sanayi Ltd. Sti. Samsun Serbest Bolgesi Subesi</b> Serbest Bolge, E Ada, 2 Parsel, Limanici, Samsun, Turkey</p>	<ul style="list-style-type: none"> <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

<b>Establishment</b>	<b>Status of Issue</b>	<b>Source of Information under Review</b>	<b>Primary Reason for Action</b>
<p><b>Jubilant Generics (Roorkee)</b> Village Sikandarpur Bhainswal, Roorkee Dehradun Highway , Bhagwanpur, Roorkee District Haridwar, Uttarakhand, India, 247 661</p>	<ul style="list-style-type: none"> <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
<p><b>LNK International Inc.</b> 22 Arkay Drive, Hauppauge, NY, 11788, United States</p>	<ul style="list-style-type: none"> <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

<b>Establishment</b>	<b>Status of Issue</b>	<b>Source of Information under Review</b>	<b>Primary Reason for Action</b>
<p><b>LNK International Inc.</b> 40 Arkay Drive, Hauppauge, NY, 11788, United States</p>	<ul style="list-style-type: none"> <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
<p><b>LNK International Inc.</b> 60 Arkay Drive, Hauppauge, NY, 11788, United States</p>	<ul style="list-style-type: none"> <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

<b>Establishment</b>	<b>Status of Issue</b>	<b>Source of Information under Review</b>	<b>Primary Reason for Action</b>
<p><b>LNK International Inc.</b> 100 Ricefield Lane, Hauppauge, NY, 11788, United States</p>	<ul style="list-style-type: none"> <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
<p><b>LNK International Inc.</b> 145 Ricefield Lane, Hauppauge, NY, 11788, United States</p>	<ul style="list-style-type: none"> <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

<b>Establishment</b>	<b>Status of Issue</b>	<b>Source of Information under Review</b>	<b>Primary Reason for Action</b>
<p><b>Lupin Limited Unit 1</b> Unit 1, 198-202 New Ind Area No 2, Mandideep Madhya Pradesh, India</p>	<ul style="list-style-type: none"> <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
<p><b>Marcus Research Laboratory Inc.</b> 1820 Delmar Blvd, St. Louis, MO, 63103, United States</p> <p><b>NEW</b></p>	<ul style="list-style-type: none"> <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

<b>Establishment</b>	<b>Status of Issue</b>	<b>Source of Information under Review</b>	<b>Primary Reason for Action</b>
<p><b>Mylan Unit 7</b> Plot No. 14, 99 &amp; 100, IDA, Pashamylaram Phase II, Patancheru, Sangareddy District, Telangana, 502307, India.</p>	<ul style="list-style-type: none"> <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
<p><b>Mylan Laboratories Limited</b> Unit 8, G. Chodavaram, POO Sapatirega Mandal, Vizianagaram District, Andhra Pradesh, 535204, India</p>	<ul style="list-style-type: none"> <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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<p><b>Novel Laboratories, Inc.</b> 400 Campus Drive, Somerset, NJ, 08873, United States</p>	<ul style="list-style-type: none"> <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
<p><b>PAB Organics Private Limited</b> 101-103, GIDC, Nandesari, Vadodara, Gujarat, 391340, India</p> <p><b>NEW</b></p>	<ul style="list-style-type: none"> <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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<p><b>PCCA, Inc</b> 9901 South Wilcrest, Houston, TX, 77099, United States</p>	<ul style="list-style-type: none"> <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
<p><b>Shandong Xinhua Pharmaceutical Co., Ltd</b> Hutian Chemical Industrial Zone, Zibo, Shandong, 255075, China</p>	<ul style="list-style-type: none"> <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
<p><b>Tender Corporation</b>                      944 Industrial Park Rd,                      Littleton, New Hampshire,                      03561-3956, United States</p>	<ul style="list-style-type: none"> <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
<p><b>Toyobo Co Ltd</b>                      1-1 Katata 2-chom Otsu                      Pharmaceuticals Plant,                      Otsu-shi, Siga, 520-0292,                      Japan</p>	<ul style="list-style-type: none"> <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**

Establishment 	Status of Issue 	Source of Information under Review 	Primary Reason for Action 
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Establishment  	Status of Issue  	Source of Information under Review  	Primary Reason for Action  
<p><b>Acharya Chemicals</b> W41 &amp;W42, MIDC Industrial estate - Morivali Village, 421501 AMBARNATH (W) (Dist Thane), 42150, India</p>	<ul style="list-style-type: none"> <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
<p><b>Actavis Laboratories, FL. Inc.,</b> 4955 Orange Drive, Davie, Fort Lauderdale, Florida, USA, 33314</p>	<ul style="list-style-type: none"> <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>• Medically necessary products identified.</li> <li>• Issued terms and conditions to Canadian importer(s)</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  
<p><b>Agila Onco Therapies Ltd.</b> Plot No. 284/B Bommasandra Jigani Link Road, Industrial Area, Bangalore, Kamataka, India</p>	<ul style="list-style-type: none"> <li>• Non-compliant rating issued</li> <li>• No further action required by Health Canada at this time</li> </ul> <p>Related recalls and alerts:</p> <ul style="list-style-type: none"> <li>• <a href="#"><u>Methotrexate Injection USP 50 mg/2 mL - Voluntary Recall Due to the Potential Presence of Foreign Particulate Matter</u></a></li> </ul>	<ul style="list-style-type: none"> <li>• Regulatory Partner(s)</li> <li>• Canadian importer(s)</li> </ul>	<p>General GMP observations</p>
<p><b>AGILA SPECIALTIES PRIVATE LTD.</b> Opp II M, Bilekahalli, Bannerghatta Road, Bangalore, Karnataka, India - 560 076</p>	<ul style="list-style-type: none"> <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>	<p>Regulatory Partner(s)</p>	<p>General GMP observations</p>

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<p><b>AGILA SPECIALTIES PRIVATE LTD., SPECIALTY FORMULATION FACILITY (SFF)</b>            19A, Plot No. 284-B/1 Bommasandra Jigani Link Road, Anekal Taluk, Bangalore India - 560 105</p>	<ul style="list-style-type: none"> <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>• Medically necessary products identified</li> <li>• Requested voluntary quarantine of non-medically necessary products</li> <li>• Voluntary quarantine in place</li> <li>• Issued terms and conditions to Canadian importer(s)</li> <li>• No further action required by Health Canada at this time</li> </ul>	Regulatory Partner(s)	General GMP observations

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<b>Akorn Inc.</b> 1222 West Grand Ave Decatur, IL USA, 62522-1412	<ul style="list-style-type: none"> <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
<b>Akorn Inc.</b> 72 Veronica Ave, Somerset NJ, 08873, USA	<ul style="list-style-type: none"> <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

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<p><b>AllerQuest LLC</b> 10 Farmington Valley Drive, Suite 106 Plainville, Connecticut 06062-1182, United States</p>	<ul style="list-style-type: none"> <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>• Medically necessary products identified</li> <li>• Terms and Conditions applied</li> </ul>	Regulatory Partner(s)	General GMP observations
<p><b>Amanta Healthcare Ltd.</b> Plot No 876 NH No 8, Hariyala Matar Kheda, Gujarat, 387411, India</p>	<ul style="list-style-type: none"> <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>• Medically necessary products identified</li> <li>• Issued terms and conditions to Canadian importer(s)</li> <li>• No further action required by Health Canada at this time</li> </ul>	Regulatory Partner(s)	General GMP observations

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<b>Antibioticos do Brasil</b> Rod. Professor Zeferino Vaz, Km135- SP332, Cosmopolis, Sao Paulo, Brazil 13150-000	<ul style="list-style-type: none"> <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>• Medically necessary products identified</li> <li>• Issued terms and conditions to Canadian importer(s)</li> </ul>	Regulatory Partner(s)	General GMP observations

**Date modified:**

2021-11-12