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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: **October 1, 2020**

## Open Items

<b>Establishment</b>	<b>Status of Issue</b>	<b>Source of Information under Review</b>	<b>Primary Reason for Action</b>
<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>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
<p><b>Glenmark Pharmaceuticals Limited</b> Village Kishanpura Baddi Nalagarh Road Baddi Solan, Himachal 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> <li>• No medically necessary products identified at this time</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>Guangzhou Tinci Materials Technology Co. Ltd.</b> No.8 Kangda Road, Yunpu Industrial Zone, Huangpu Region</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>Kumar Organic Products Limited</b> Plot No. 379, Maitri Marg, Canal Road, Luna, Taluk Padra, Vadodara, 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>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> </ul>	Regulatory Partner(s)	General GMP observations
<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> </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> 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> </ul>	Regulatory Partner(s)	General GMP observations
<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> </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> 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> </ul>	Regulatory Partner(s)	General GMP Observations
<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

<b>Establishment</b>	<b>Status of Issue</b>	<b>Source of Information under Review</b>	<b>Primary Reason for Action</b>
<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
<p><b>Pfizer Healthcare India Pvt. Ltd.</b> Plot No. 111 (Part), 116, 117, 118, 119 and 123 (Part), Jawaharlal Nehru Pharma City, Special Economic Zone, Parawada Mandal, 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>Sentiss Pharma Private Limited</b> Village Khera Nihla, Tehsil Nalagarh, Dist: Solan Khera Nihla, Himachal Pradesh 174101, 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>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

<b>Establishment</b>	<b>Status of Issue</b>	<b>Source of Information under Review</b>	<b>Primary Reason for Action</b>
<p><b>Stason Pharmaceuticals Inc.</b> 11 Morgan, Irvine, CA, 92618, 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>Strides Pharma Science Limited</b> Unit-II, R. S. No.: 32, 33 &amp; 34 PIMS Road Periyakalpet, Puducherry</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>Symbiotec Pharmalab Pvt. Ltd.</b> 385/2 Pigdamber, Near Hotel Mashal, Off A.B. Road, Rau, Indore, Madhya Pradesh, 453331, 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>Teligent Pharma US, LLC</b> 105 Lincoln Avenue, Buena, NJ, 08310, 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

<b>Establishment</b>	<b>Status of Issue</b>	<b>Source of Information under Review</b>	<b>Primary Reason for Action</b>
<p><b>Zhejiang Huahai Pharmaceutical Co., Ltd. - Chuannan Site</b> Coastal Industrial Zone, Duqiao, Linhai, Zhejiang, 317016, China</p>	<ul style="list-style-type: none"> <li>• Canadian importer(s) contacted by Health Canada for information</li> <li>• Health Canada has completed a GMP assessment and assessed the site as non-compliant</li> <li>• Importers cannot import drugs that contain active pharmaceutical ingredients from this site</li> <li>• Health Canada is continuing to review information as it becomes available</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>Zhejiang Hisun Pharmaceutical Co., Ltd.</b> 1 Haizheng Road, Jiaojiang District, Taizhou City, Zhejiang, 318 000, China</p> <p>Inspection start date: 2019-03-26</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>Zhejiang Hisun Pharmaceutical Co., Ltd.</b> 56 Binhai Road, Jiaojiang District, Taizhou City, Zhejiang, 318 000, China</p> <p>Inspection start date: 2019-03-26</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>	<p>Regulatory Partner(s)</p>	<p>General GMP observations</p>
<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>	<ul style="list-style-type: none"> <li>• Regulatory Partner(s)</li> </ul>	<p>General GMP observations</p>









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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<p><b>Akorn Inc.</b> 1222 West Grand Ave Decatur, IL USA, 62522-1412</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>Akorn Inc.</b> 72 Veronica Ave, Somerset NJ, 08873, USA</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

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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>	<p>Regulatory Partner(s)</p>	<p>General GMP observations</p>

Establishment  	Status of Issue  	Source of Information under Review  	Primary Reason for Action  
<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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<p><b>Antibioticos do Brasil</b> Rod. Professor Zeferino Vaz, Km135-SP332, Cosmopolis, Sao Paulo, Brazil 13150-000</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> </ul>	Regulatory Partner(s)	General GMP observations

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**Date modified:**

2020-10-01