

Commissioner Dr. Scott Gottlieb  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
Submitted electronically to [CommissionerFDA@fda.hhs.gov](mailto:CommissionerFDA@fda.hhs.gov)

Dear Commissioner Gottlieb:

I am writing to bring your attention to serious concerns about the pending acquisition of a substantial share in the nutrition retailer GNC by the Chinese pharmaceutical company Harbin Pharmaceutical Group Holding (also known as “Hayao”).<sup>1</sup> We believe that this transaction may be detrimental to the American people because of Harbin’s history of regulatory shortcomings in China. As the nation’s top regulator of pharmaceuticals and dietary supplements, we urge you to investigate the pending purchase.

### *Harbin’s Purchase of GNC Stock*

The proposed purchase of GNC shares by Harbin was announced in February of this year. According to GNC, under the terms of the agreement Harbin would invest \$300 million in GNC, and create a joint venture for manufacturing, marketing, sale and distribution of GNC-branded products in China. The deal would make Harbin the largest shareholder in GNC (on an as converted basis). CITIC Capital Holdings Limited, a major shareholder of Harbin, supported the transaction.<sup>2</sup>

GNC and Harbin reached an agreement in November for the funding of the investment to be completed by February 2019.<sup>3</sup> In connection with the investment, the GNC board will be expanded to 11 members including five members from GNC, five members from Harbin and GNC CEO Ken Martindale.<sup>4</sup>

### *Ownership of Harbin*

Harbin is partially owned by the government of China, and partially by private owners. The largest direct shareholder in Harbin is the government of Harbin municipality, in Heilongjiang province, which owns 45% of the company.<sup>5</sup> CITIC Capital, a private equity company, controls another 45% of Harbin’s stock indirectly through three subsidiaries.<sup>6</sup>

### *Regulatory Citations and Sanctions of Drugs Produced by Harbin*

In China, Harbin has been cited or sanctioned by government agencies for problems with its drugs no fewer than 6 times since 2015, and three times in 2018 alone:

1. **June 2015** – In a report by China’s Ministry of Agriculture on a veterinary drugs quality control inspection, penicillin produced by Harbin Pharmaceutical was listed for irregularities.<sup>7</sup>
2. **July 2015** – The National Food and Drug Administration of China issued its Notice on the Investigation on Companies Using Gingko Leaves Extract for Manufacturing Health Supplements.<sup>8</sup> According to the Notice, Harbin Pharmaceutical used substandard ginkgo extracts to produce its Gingko Soft Pill. In two inspections led by the company itself, the product was shown to have quality issues. The Notice also stated that the company took measures to mitigate the issue and to withdraw products with quality issues.<sup>9</sup>

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D. TAYLOR, PRESIDENT

GENERAL OFFICERS: Gwen Mills, Secretary-Treasurer • Peter Ward, Recording Secretary  
Jo Marie Agriesti, General Vice President • Maria Elena Durazo, General Vice President for Immigration, Civil Rights and Diversity

3. **November 2016** – Harbin Pharmaceutical was sanctioned by the Food and Drug Administration of Heilongjiang province for failing to meet food regulation standards on certain products it manufactured.<sup>10</sup>
4. **January 2018** – According to a government website, the Heilongjiang provincial Food and Drug Administration sanctioned Harbin Pharmaceutical due to the presence of ammonium in certain of its drugs in excess of regulatory limits. Reportedly, this was the second time within six months that Harbin Pharmaceutical and its subsidiaries were sanctioned for this problem.<sup>11</sup>
5. **July 2018** – A notice published by the National Food and Drug Administration of China stated that Harbin Pharmaceutical had again been found guilty of failing to meet regulatory standard for its Siberian ginseng granule, according to news site Ifeng.<sup>12</sup>
6. **August 2018** – The National Food and Drug Administration of China found that Harbin Pharmaceutical’s medicinal Chinese licorice was not meeting regulatory standards.<sup>13</sup>

Harbin products which have been cited by the Chinese government have included ginkgo pills, Siberian ginseng, and Chinese licorice. According to GNC’s website, the company sells similar products (ginkgo pills,<sup>14</sup> Siberian root,<sup>15</sup> and licorice root<sup>16</sup>) to consumers in the United States.

With this track record, we do not think it is appropriate for Harbin to own a substantial portion of a significant vitamin and supplement retailer in the United States. We urge you to investigate this acquisition.

Sincerely,

Jeff Nelson  
Deputy Director  
UNITE HERE  
jnelson@unitehere.org

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<sup>1</sup> Harbin Pharmaceutical Group Holding has a partially-owned subsidiary named Harbin Pharmaceutical Group. References to ‘Harbin’ in this letter are to the holding company.

<sup>2</sup> “GNC And Harbin Pharmaceutical Announce \$300 Million Strategic Investment And China Joint Venture,” GNC, 2/13/18. <https://gnc.gcs-web.com/news-releases/news-release-details/gnc-and-harbin-pharmaceutical-announce-300-million-strategic>.

<sup>3</sup> “GNC and Hayao Reach Agreement for Funding of \$300 Million Strategic Investment,” GNC, 11/7/18. <https://gnc.gcs-web.com/news-releases/news-release-details/gnc-and-hayao-reach-agreement-funding-300-million-strategic>.

<sup>4</sup> “GNC And Harbin Pharmaceutical Announce \$300 Million Strategic Investment And China Joint Venture,” GNC, 2/13/18. <https://gnc.gcs-web.com/news-releases/news-release-details/gnc-and-harbin-pharmaceutical-announce-300-million-strategic>.

<sup>5</sup> National Enterprise Credit Information Publicity System, “哈药集团有限公司”, State Administration for Industry and Commerce, retrieved 9/07/18.

<sup>6</sup> (A) According to information disclosed to SAIC, 中信资本冰岛投资有限公司, 华平冰岛投资有限公司 and 黑龙江中信资本医药产业股权投资合伙企业 owns 45% of 哈药集团有限公司, see National Enterprise Credit Information Publicity System, “哈药集团有限公司”, State Administration for Industry and Commerce, retrieved 9/07/18 ; (B) According to the Group’s English Webpage, Harbin Pharmaceutical Group Holding Co. Ltd. is the

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English name of 哈药集团有限公司, see Home, Harbin Pharmaceutical Group Holding Co. Ltd., retrieved 11/7/18, <http://en.hayao.com/>; (C), 中信资本冰岛投资有限公司, 华平冰岛投资有限公司 and 黑龙江中信资本医药产业股权投资合伙企业 are subsidiaries of CITIC Capital, see “哈药集团股份有限公司关于中信资本股权投资（天津）股份有限公司要约收购事宜进展情况的公告”, Harbin Pharmaceutical Group Co., Ltd., 2/24/18, [http://static.sse.com.cn/disclosure/listedinfo/announcement/c/2018-02-24/600664\\_20180224\\_1.pdf](http://static.sse.com.cn/disclosure/listedinfo/announcement/c/2018-02-24/600664_20180224_1.pdf).

<sup>7</sup> “一季度 115 批兽药质量不合格 哈药兽药上黑榜”, Xinhua, 6/11/15, [http://www.xinhuanet.com//food/2015-06/11/c\\_127906034.htm](http://www.xinhuanet.com//food/2015-06/11/c_127906034.htm)

<sup>8</sup> “哈药总厂卷入“银杏叶事件” 购入 2 吨不合格原料”, Yicai, 7/8/15, <https://www.yicai.com/news/4642218.html>

<sup>9</sup> “哈药总厂卷入“银杏叶事件” 购入 2 吨不合格原料”, Yicai, 7/8/15, <https://www.yicai.com/news/4642218.html>

<sup>10</sup> “半年两子公司被查出售劣“白矾”哈药集团屡登质量“黑榜””, China.com.cn, 1/16/18,

<http://finance.china.com.cn/news/20180116/4510693.shtml>

<sup>11</sup> “半年两子公司被查出售劣“白矾”哈药集团屡登质量“黑榜””, China.com.cn, 1/16/18,

<http://finance.china.com.cn/news/20180116/4510693.shtml>

<sup>12</sup> “哈药集团药品被查不合格 屡被点名可还行”, Ifeng, 7/30/18,

[http://tech.ifeng.com/a/20180730/45091019\\_0.shtml](http://tech.ifeng.com/a/20180730/45091019_0.shtml)

<sup>13</sup> “61 家药企甘草饮片被召回 哈药集团世一堂上“黑榜””, Sina, 8/6/18,

[http://k.sina.com.cn/article\\_6307772617\\_177f8f8c90190096uy.html](http://k.sina.com.cn/article_6307772617_177f8f8c90190096uy.html)

<sup>14</sup> GNC Herbal Plus® Ginkgo Biloba 120MG, GNC, retrieved 10/31/18. <https://www.gnc.com/ginkgo-biloba/183412.html>.

<sup>15</sup> GNC HERBAL PLUS® SIBERIAN ROOT 500 MG, GNC, retrieved 11/1/18.

<https://www.gnc.com/ginseng/483502.html>.

<sup>16</sup> Nature's Answer® Licorice 450mg, GNC, retrieved 10/31/18. <https://www.gnc.com/expanded-assortment-shop-all/792874.html>