August 11, 2014

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket No. FDA-2014-D-0609
Draft Guidance for Industry on Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification

Dear Sir or Madam:

Novo Nordisk welcomes this opportunity to comment on the *Draft Guidance for Industry on Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification*. Novo Nordisk supports the issuance of this draft guidance, which creates a process for illegitimate product notifications and will aid industry in identifying scenarios that could significantly increase the risk of a suspect product entering the distribution supply chain.

Novo Nordisk is a pioneer in biotechnology, a world leader in diabetes care and holds a leading position within hemostasis management, growth hormone therapy, and hormone therapy for women. Novo Nordisk manufactures and markets pharmaceutical products and services that make a significant difference to our patients, the medical profession, and society.

After reviewing the draft guidance, we have identified certain areas that we would like to clarify with FDA. We agree with the draft guidance that trading partners must discuss with each other any observations or concerns they may have regarding the authenticity of a drug product. As contemplated by the DSCSA, we urge FDA to emphasize within the guidance that trading partners should always involve and coordinate with the drug manufacturer before making a determination that a manufacturer's drug product is suspect or illegitimate. Our specific comments are provided on the following pages.

Novo Nordisk Inc.
PO Box 846
Plainsboro, NJ 08536
609-987-5800
www.novonordisk-us.com

Specific Comments

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III. Identification of Suspect Product		
3	102-108	As set forth in the draft guidance, "trading partners must have systems in place that enable them, upon determining that a product in their possession or control is suspect or upon receiving a request for verification from the FDA, to quarantine suspect product and promptly conduct an investigation, in coordination with other trading partners, as applicable, to determine whether a suspect product is illegitimate." This language as drafted implies that trading partners must quarantine product when receiving requests for verification from the FDA. However, it is our interpretation of the DSCSA that an FDA request for verification does not immediately require quarantine of product unless a determination is made by the FDA that the product is suspect. For example, FDCA § 582(b)(4)(A)(i) reads: "Upon making a determination that a product within the possession or control of a manufacturer is a suspect product, or upon receiving a request from verification from the Secretary *that has made a determination that a product within the possession or control of a manufacturer is a suspect product*, a manufacturer shall (I) quarantine such product . . . ." (emphasis added) (*see also* FDCA §§ 582(c)(4)(A)(i), 582(d)(4)(A)(i) and 582(e)(4)(A)(i)). We request that the Agency clarify this language in the final guidance to make clear that quarantine is triggered by a request for verification from FDA where FDA has determined that a product is suspect.

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6	217-225	As set forth in the draft guidance, "trading partners should discuss with each other any observations, questions, or concerns they have related to the status of a drug as a suspect product to aid them in determining whether the drug should be considered a suspect product." Indeed, the DSCSA requires that trading partners coordinate with the manufacturer when making illegitimate product determinations. (*See, e.g.*, FDCA §§ 582(c)(4)(B)(i), 582(d)(4)(B)(i) and 582(e)(4)(B)(i)). As such, we strongly recommend that the guidance specifically provide that trading partners should consult and coordinate with the manufacturer *before* making a determination that a manufacturer's drug product is suspect or illegitimate. Manufacturers have the greatest knowledge and technical expertise about the authenticity of their products, product appearance and packaging, and as such are best positioned to make suspect and illegitimate product determinations. Not only would this serve to reduce the number of inaccurate reports of illegitimate products to FDA, it may avoid unnecessary disruptions of medicines to patients especially given that illegitimate product determinations trigger quarantine requirements.
IV. Notification of Illegitimate Product		
7	264-269	As noted by FDA in the draft guidance, the DSCSA requires trading partners to notify FDA of illegitimate product determinations and also requires manufacturers to make notifications for high risk of illegitimacy determinations. While the draft guidance provides that manufacturers use Form 3911 to notify FDA of high risk of illegitimacy determinations, Form 3911 does not appear to address such notifications. Rather, the form presupposes that a product has been determined to be illegitimate, e.g., "Date Illegitimate Product Was Determined by Company" and "Description of Illegitimate Product." Thus, we recommend that Form 3911 include provisions for "high risk of illegitimacy" notifications.

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7	264-269	As noted above, trading partners are required to notify the FDA of illegitimate product determinations and manufacturers are additionally required to notify FDA of high risk of illegitimacy. This could give rise to duplicate notifications to FDA for the same product. Because duplicate reporting could prove to be an unnecessary burden to the Agency and trading partners, we suggest that FDA implement controls or clarify the process to avoid duplicate notifications. We believe that this risk would be minimized by our recommendation to require trading partners to consult and coordinate with the manufacturer before making a determination that a product is illegitimate.
8	327-329	As set forth in this section, "FDA intends to respond to requests for termination within 10 business days of submission" when responding to trading partners regarding terminations of illegitimate or high risk of illegitimacy notifications. FDA advises that it may require more than 10 days to respond in some cases. An additional 10 days or longer of quarantine may create unnecessary delays in getting important, life-saving medicines to patients. The DSCSA requires trading partners to notify FDA within 24 hours (and immediate trading partners where there is reason to believe the trading partner may have received such illegitimate product) when a determination has been made that a product is illegitimate (*see, e.g.*, § 582(b)(4)(B)(ii)(I)) or in the case of a manufacturer, there is a high risk of illegitimacy (*see, e.g.*, § 582(b)(4)(B)(ii)(II)). In addition, FDA will be in communication with trading partners regarding background and developments with the case and therefore may not require 10 days to evaluate the termination request. We respectfully request that the guidance require FDA to respond to trading partners within 3 business days.

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609-987-5800
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	General	The DSCSA requires trading partners to promptly notify the FDA, as applicable, when there is a determination that a suspect product is not an illegitimate product (i.e, "cleared product"). (*See* §§ 582(b)(4)(A)(ii); (c)(4)(A)(ii); (d)(4)(A)(iii) and (e)(4)(A)(ii)). We request that FDA provide guidance and suggest a process by which trading partners may notify the Agency when a determination has been made that a suspect product is not an illegitimate product. We recommend that the guidance allow trading partners to notify the Secretary by using existing systems and processes, such as phone or e-mail, for making such "cleared product" communications.

Thank you for the opportunity to provide comments on the draft guidance. We would be pleased to provide further input or clarification of our comments if needed.

Sincerely,

Robert B. Clark
Vice President, Regulatory Affairs
Novo Nordisk Inc.

Novo Nordisk Inc.
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Plainsboro, NJ 08536
609-987-5800
www.novonordisk-us.com