

November 19, 2020

Mr. Jimmy Heisel
National Sales Manager
Pharmacosmos, Inc.
776 Mountain Boulevard
Watchung, NJ 07069 USA

RE: Temporary Importation of Uniferon® Solution for Injection, 200 mg/mL x 100-mL Product to the U.S. by Pharmacosmos A/S, located in Holbæk, Denmark, in Accord with the U.S. FDA No Objection Provisions for an Injectable Iron Animal Drug Shortage

Dear Mr. Jimmy Heisel:

This transmittal letter and the revised and attached *Uniferon® Customer Information Sheet* must accompany each shipment of each of the first 5 lots of an approximate total of 100,000 units of the Uniferon® Solution for Injection, 200 mg/mL x 100-mL glass vial product being shipped to Pharmacosmos, Inc.; to the product being shipped to the Pharmacosmos, Inc. customers. The distributor customers must distribute the *Uniferon® Customer Information Sheet* to the product being shipped from the distributors to their end-user customers in the U.S.

Please note that the *Uniferon® Customer Information Sheet* has been revised in accord with the input and requirements of the U.S. FDA. This informative document should be referenced by Pharmacosmos, Inc.; the Pharmacosmos, Inc. distributor customers; and the distributor end-user customers of the Uniferon® Solution for Injection, 200 mg/mL x 100-mL product.

Please note that during the injectable iron animal drug shortage period in the U.S, the Uniferon® Solution for Injection, 200 mg/mL x 100-mL product is being manufactured for Pharmacosmos A/S by an EU authorized manufacturer; however, this product is not approved by FDA.

This current shipment is comprised of the two lots described below:

- Lot Number 3092015 manufactured October 2020 with an expiry of October 2022: 272 Master Shipper Cartons x 72 x 100-mL glass vials = 19,584 Uniferon® Solution for Injection, 200 mg/mL x 100-mL glass vials of product.
- Lot Number 3092016 manufactured October 2020 with an expiry of October 2022: 272 Master Shipper Cartons x 72 x 100-mL glass vials = 19,584 Uniferon® Solution for Injection, 200 mg/mL x 100-mL glass vials of product.
- Pharmacosmos A/S NDC #'s:
 - The 100-mL glass vials: 49442-7401-1
 - The 12 x 100-mL intermediate shipper cartons: 49442-7401-2
 - The 72 x 100-mL master shipper cartons: 49442-7401-3

Pharmacosmos, Inc., a fully owned U.S. subsidiary of Pharmacosmos A/S, will assume the acceptance of the incoming of the product from the New York Port of Entry, and will also assume all administrative handling and shipment responsibilities for the two lots of product to the U.S. distributor customer identified and located at the address presented below. The entire shipment delineated in the above referenced listings of the two lots will shipped to the following distributor customer:

Ag ProVision, LLC
277 Faison McGowan Road,
Kenansville, NC 28349

Pharmacosmos A/S
Roervangsvej 30
DK-4300 Holbæk
Denmark

T: +45 5948 5959
F: +45 5948 5960
E: info@pharmacosmos.com
W: pharmacosmos.com

CVR No.: DK15517085

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When Ag ProVision, LLC receives the shipment of Uniferon® Solution for Injection, 200 mg/mL x 100-mL product, this distributor customer will assume the responsibility for including a copy of the revised Uniferon® Customer Information Sheet with each shipment of each of the two above referenced lots of product. Ag ProVision, LLC will also assume the responsibility for including a copy of the revised Uniferon® Customer Information Sheet for any additional shipments of these two lots of product throughout its channels of distribution.

The original Uniferon® Customer Information Sheet was revised in accord with input and the requirements of the U.S. FDA, whereby the revision of the document occurred after the labeling and packaging of the two lots of Uniferon Solution for Injection, 200 mg/mL x 100-mL product was already completed.

In summary, copies of the document delineated below should be included along with for each shipment of each of the above referenced two lots of product by Pharmacosmos, Inc. to Ag ProVision, LLC; and to each shipment of each lot of the two above referenced two lots of product throughout the Ag ProVision, LLC channels of distribution to its end-user customers:

- The revised Uniferon® Customer Information Sheet

Thank you for your support.

Best regards from

Ingeborg Lohmann Laursen

VP Quality and Regulatory Affairs

Pharmacosmos A/S

