URGENT DRUG RECALL

Azacitidine for Injection 100mg/vial

INITIATED 07/20/2022

Teva Pharmaceuticals USA, Inc.

NDC 1 vial / carton	Lot Number	Expiration Date
68001-0313-56	FE22001A	01/2024

Dear BluePoint™ Laboratories:

Teva Pharmaceuticals USA, Inc. (Teva USA) is voluntarily recalling one lot of Azacitidine for Injection 100mg/vial Lyophilized Powder to the RETAIL LEVEL. Teva manufactured and distributed the recall product exclusively to you under your BluePoint™ Laboratories label. Teva USA exclusively shipped lot # FE22001A to you on 28 February 2022.

Teva USA initiated this recall because of an out of specification assay result obtained during stability testing for the subject lot # FE22001A. Specifically, the assay results are below the specification limit. The safety concern that may arise from the lower content of Azacitidine is decreased efficacy of the product. The product indications are for treatment of patients with FAB myelodysplastic syndrome (MDS) subtypes: Refractory anemia (RA) or refractory anemia with ringed sideroblasts (RARS) (if accompanied by neutropenia or thrombocytopenia or requiring transfusions), refractory anemia with excess blasts (RAEB), refractory anemia with excess blasts in transformation (RAEB-T), and chronic myelomonocytic leukemia (CMMoL). Teva's Health Hazard Assessment determined the risk of harm to patients as severe (i.e., not immediately life threatening but hospitalization or prolongation of hospitalization indicated; disabling) although the likelihood of harm is determined to be remote (i.e., unlikely, although conceivable).

Please take the following activities that are necessary for this recall:

1. Immediately examine your inventory for lot # FE22001A of Azacitidine for Injection 100mg/vial Lyophilized Powder, quarantine the product and immediately cease distribution of the Product.
2. **Please perform a SUB-RECALL to your direct accounts indicating this market action is Retail Level. Teva recommends using this Recall Notification and Stock Response Form (SRF) as a basis of your recall notification.**
3. Promptly complete the enclosed SRF, *even if you have **no** product to return*. The completed SRF should include name and location of your recall processor and your plans for final disposition of the product.
4. Return your completed SRF by mail, email, or FAX to Inmar, Attn: Recall Coordinator,

   Inmar, 635 Vine Street, Winston Salem, NC 27101.
   Email address: **rxrecalls@inmar.com.**
   FAX: 817-868-5362.

CONTACT INFORMATION
Inmar – Teva's Recall Processor Live calls received: M - F, 9:00 AM - 5:00 PM Eastern Time 855-946-7288
Medical-related Questions or to report an Adverse Event: Contact Medical Information at: 888-838-287, option 3, then, option 4 Live calls received: M - F, 9:00 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week Or Email: druginfo@tevapharm.com
Product Quality Complaint-related Questions: Contact Quality Assurance Services: 888-838-2872, option 4 Live calls received: M - F, 9:00 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week
Customer Service-related Questions: Contact Teva Customer Service: 888-838-2872, option 3 then, option 2 Live calls received: M - F, 8:30 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week
FDA contact information for reporting adverse events/quality complaints: Online at www.fda.gov/medwatch/report.htm or call FDA at 1-800-FDA-1088

This recall is being made with the knowledge of the Food and Drug Administration.

Sincerely,

Regulatory Compliance, Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL

Azacitidine for Injection 100mg/vial

INITIATED 07/20/2022

Teva Pharmaceuticals USA, Inc.

STOCK RESPONSE FORM / BUSINESS REPLY FORM

Enter the information of the recalled product to be returned in the table below. If additional space is needed, please make copies of this form.

****DEA # is required in order to process your form.***

Customer Name: **BluePoint™ Laboratories (BPL)**	Date:	
Does this response include **all** DC locations?	☐ YES	☐ NO
*DEA #:	*Debit Memo #	
Address:		
City:	State:	Zip:
Contact Name:	Telephone #:	

Carton NDC 1 vial / carton	Lot Number	Expiration Date	Quantity on Hand at BPL DC
68001-0313-56	FE22001A	01/2024	

I HAVE CHECKED MY STOCK AND:

☐ I **do not** have stock of the recalled item(s) **OR** ☐ I **do** have stock of the recalled item(s) above.

FINAL DISPOSITION OF RECALLED MERCHANDISE RETURNS
BluePoint™ Laboratories intends to collect recalled merchandise returns at their recall processor. ☐ YES ☐ NO
*Name and Location Blue Point™ Laboratories' Recall Processor
Destruction of Recalled Merchandise Returns (Check One) ☐ Blue Point™ Laboratories' will coordinate the destruction of all recalled merchandise returns through its recall processor and provide Teva with written evidence of destruction. ☐ Blue Point™ Laboratories' (BPL) will coordinate with Teva for the destruction of all recalled merchandise returns through Teva's recall processor, Inmar. Shipping labels to return recalled merchandise will be requested by BPL by contacting Inmar at 855-946-7288. BPL may request written evidence of destruction from Teva.

Please return this form by FAX to: 817-868-5362 or by E-mail at: rxrecalls@inmar.com or Mail to:
Inmar, Attn: Recall Coordinator, Inmar, 635 Vine Street, Winston Salem, NC 27101.

Inmar/MedTurn Use Only:				
Scan	Labels	Store	Kit	D.B