

June 14, 2021

***BY ELECTRONIC DELIVERY***

Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**RE: FDA-2020-P-0102**

This letter serves as the official withdrawal of Citizen Petition FDA-2020-P-0102.

Regards,

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**Appendix 1: IVQIA Data**

DISTRIBUTOR	NDC	ANDA	October 2017 - September 2018 Eaches	October 2018 - September 2019 Eaches	Grand Total
AMERICAN HEALTH PACKAGING	60687040583	202496	-	7,004,820	
GSMS INC.	60429097530	202496	1,158,990	1,683,900	
GSMS INC.	60429097560	202496	91,320	221,100	
MYLAN PHARMACEUTICALS, INC.	378967130	202496	24,998,640	20,527,620	
MYLAN PHARMACEUTICALS, INC.	378967131	202496	73,243,393	77,041,938	
MYLAN PHARMACEUTICALS, INC.	378967160	202496	899,640	696,300	
MYLAN PHARMACEUTICALS, INC.	378967191	202496	-	-	
RITEDOSE PHARMACEUTICALS, LLC	76204060030	202496	44,256,600	56,050,650	
RITEDOSE PHARMACEUTICALS, LLC	76204060060	202496	65,760,873	80,551,011	
SANDOZ	781714663	202496	1,444,800	1,078,680	
SANDOZ	781714687	202496	1,228,170	16,950	
TEVA PHARMACEUTICALS	591381715	202496	6,712,590	2,909,100	
TEVA PHARMACEUTICALS	591381766	202496	4,072,560	2,142,120	



DISTRIBUTOR	NDC	ANDA	October 2017 - September 2018 Eaches	October 2018 - September 2019 Eaches	Grand Total
		<b>Total</b>	<b>223,867,576</b>	<b>249,924,189</b>	<b>473,791,765</b>
SANDOZ	185732260	unknown	660	-	660
NEPHRON	487020101	076749	66,910,473	51,399,834	
NEPHRON	487020102	076749	-	-	
NEPHRON	487020103	076749	71,617,590	80,467,440	
NEPHRON	487020160	076749	59,442,660	61,347,180	
		<b>Total</b>	<b>197,970,723</b>	<b>193,214,454</b>	<b>391,185,177</b>
TEVA PHARMACEUTICALS	93672345	unknown	1,117	1,968	3,085
CIPLA USA, INC.	69097017353	077559	20,490,810	23,320,500	
CIPLA USA, INC.	69097017364	077559	16,657,620	16,975,500	
		<b>Total</b>	<b>37,148,430</b>	<b>40,296,000</b>	<b>77,444,430</b>