



URGENT DRUG RECALL

04/29/2021

Dear Customer,

Acella Pharmaceuticals, LLC is initiating a voluntary, nationwide, consumer level recall on 35 commercial (100-count) lots of NP Thyroid®. This recall is being conducted with the knowledge of the Food and Drug Administration. This is a targeted recall, meaning it only relates to specific lots of the medication. The list of impacted lot numbers can be found in the attached Table 1.

The products are being recalled because our testing has found these lots to be sub potent. The product contains less than 90% of the labeled amount of Levothyroxine (T4) or Liothyronine (T3). The batches were distributed by Acella Pharmaceuticals, LLC from **03/04/2020 – 03/16/2021; lot-specific distribution dates can be found in the attached Table 1 – List of Recalled Lots.**

Acella Pharmaceuticals, LLC requests that you immediately examine your inventory and quarantine product subject to recall. In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

In the next few days, each facility that received product impacted by the recall will receive a recall package by mail that will include a notification letter, a response form, and a shipping label to facilitate the return of any recalled product that remains in their inventory.

This action applies only to the NP Thyroid® NDCs and 35 lots listed in Table 1. Only product from these lots will be accepted under the terms of this recall.

If you have any general questions regarding the return of this product, please contact Qualanex via email at recall@qualanex.com or call 1-888-424-4341 (Monday through Friday from 8:00 am to 5:00 pm ET). If you have any medical questions regarding this recall, please contact Acella Pharmaceuticals, LLC at 470-550-1551 (Monday through Thursday from 9:00 am to 5:00 pm or Friday from 9:00 am to 12:30 pm ET).

We regret any inconvenience and appreciate your immediate cooperation.

A handwritten signature in black ink, appearing to read "Art Deas".

Art Deas
Chief Executive Officer
For Acella Pharmaceuticals, LLC.

See below for product labels and product images:

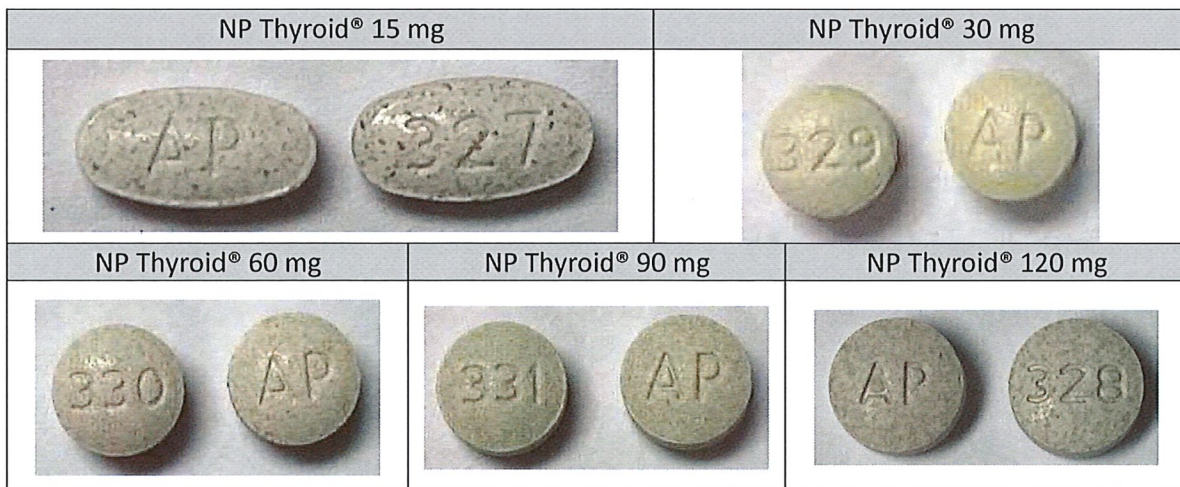
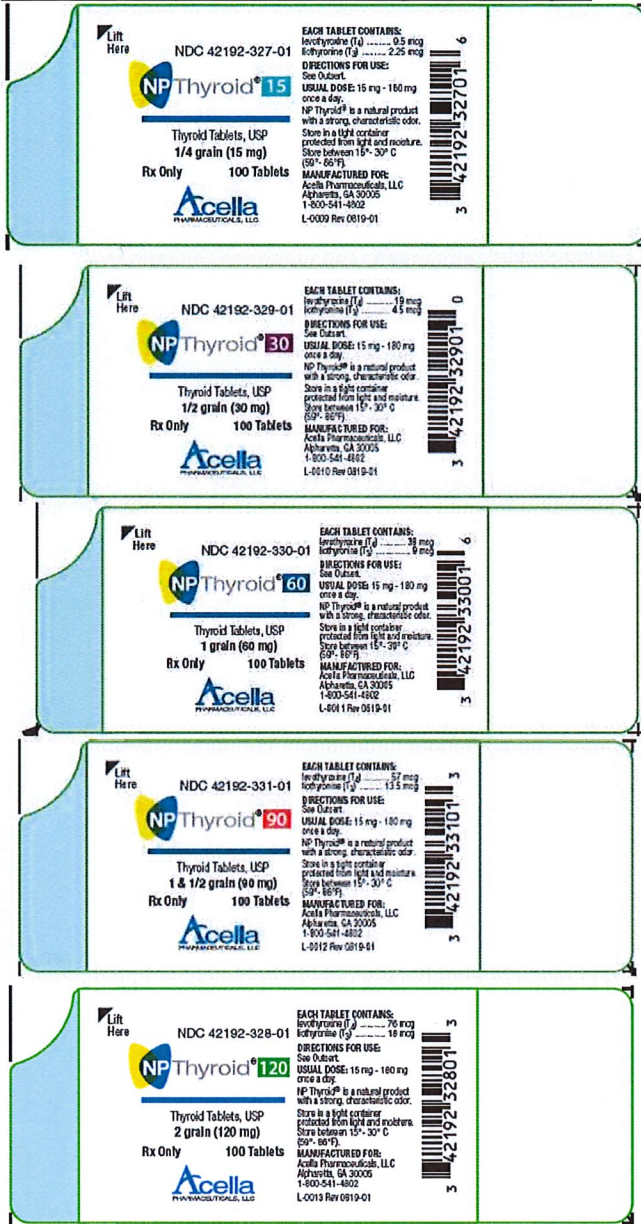


Table 1. List of 35 Recalled Commercial Lots

#	Product Description	NDC Number	Lot Number	Exp. Date	Distribution Dates
1	NP Thyroid® 15mg Tablets	42192-327-01	M327D20-1	3/31/2022	08/11/2020 - 10/06/2020
2	NP Thyroid® 15mg Tablets	42192-327-01	M327D20-3	3/31/2022	07/20/2020 - 09/29/2020
3	NP Thyroid® 15mg Tablets	42192-327-01	M327H19-3A	7/31/2021	06/23/2020 - 07/08/2020
4	NP Thyroid® 15mg Tablets	42192-327-01	M327L19-1	4/30/2021	03/04/2020 - 04/30/2020
5	NP Thyroid® 120mg Tablets	42192-328-01	M328H19-2B	8/31/2021	09/16/2020 - 09/24/2020
6	NP Thyroid® 120mg Tablets	42192-328-01	M328J19-11	8/31/2021	04/15/2020 - 06/09/2020
7	NP Thyroid® 120mg Tablets	42192-328-01	M328J19-2A	8/31/2021	07/28/2020 - 08/07/2020
8	NP Thyroid® 120mg Tablets	42192-328-01	M328J19-3A	8/31/2021	08/07/2020 - 09/02/2020
9	NP Thyroid® 120mg Tablets	42192-328-01	M328J19-4A	8/31/2021	08/31/2020 - 02/09/2021
10	NP Thyroid® 120mg Tablets	42192-328-01	M328J19-5A	8/31/2021	09/04/2020 - 11/18/2020
11	NP Thyroid® 120mg Tablets	42192-328-01	M328J19-6A	8/31/2021	09/14/2020 - 10/16/2020
12	NP Thyroid® 120mg Tablets	42192-328-01	M328J19-7A	8/31/2021	09/29/2020 - 10/14/2020
13	NP Thyroid® 120mg Tablets	42192-328-01	M328K19-2	9/30/2021	04/02/2020 - 10/02/2020
14	NP Thyroid® 120mg Tablets	42192-328-01	M328K19-4A	9/30/2021	09/25/2020 - 11/25/2020
15	NP Thyroid® 30mg Tablets	42192-329-01	M329D20-1	3/31/2022	05/12/2020 - 02/02/2021
16	NP Thyroid® 30mg Tablets	42192-329-01	M329D20-2	3/31/2022	06/22/2020 - 09/08/2020
17	NP Thyroid® 30mg Tablets	42192-329-01	M329D20-3	3/31/2022	07/13/2020 - 09/28/2020
18	NP Thyroid® 60mg Tablets	42192-330-01	M330D20-1	3/31/2022	08/11/2020 - 03/16/2021
19	NP Thyroid® 60mg Tablets	42192-330-01	M330D20-2	3/31/2022	09/25/2020 - 10/12/2020
20	NP Thyroid® 60mg Tablets	42192-330-01	M330J19-2A	8/31/2021	06/16/2020 - 06/16/2020
21	NP Thyroid® 60mg Tablets	42192-330-01	M330J19-4A	8/31/2021	07/28/2020 - 08/19/2020
22	NP Thyroid® 60mg Tablets	42192-330-01	M330J19-5A	8/31/2021	06/18/2020 - 06/24/2020
23	NP Thyroid® 60mg Tablets	42192-330-01	M330J19-6A	8/31/2021	07/01/2020 - 07/15/2020
24	NP Thyroid® 60mg Tablets	42192-330-01	M330J19-7A	8/31/2021	06/10/2020 - 06/30/2020
25	NP Thyroid® 60mg Tablets	42192-330-01	M330J19-9A	8/31/2021	05/29/2020 - 06/04/2020
26	NP Thyroid® 60mg Tablets	42192-330-01	M330K19-10	9/30/2021	03/31/2020 - 05/07/2020
27	NP Thyroid® 60mg Tablets	42192-330-01	M330K19-1A	9/30/2021	08/19/2020 - 08/26/2020
28	NP Thyroid® 60mg Tablets	42192-330-01	M330K19-9	9/30/2021	05/04/2020 - 08/26/2020
29	NP Thyroid® 90mg Tablets	42192-331-01	M331J19-10A	8/31/2021	08/19/2020 - 08/27/2020
30	NP Thyroid® 90mg Tablets	42192-331-01	M331J19-11	8/31/2021	04/03/2020 - 04/27/2020
31	NP Thyroid® 90mg Tablets	42192-331-01	M331J19-2A	8/31/2021	07/28/2020 - 08/05/2020
32	NP Thyroid® 90mg Tablets	42192-331-01	M331J19-6A	8/31/2021	09/29/2020 - 10/08/2020
33	NP Thyroid® 90mg Tablets	42192-331-01	M331K19-1	9/30/2021	04/27/2020 - 06/10/2020
34	NP Thyroid® 90mg Tablets	42192-331-01	M331K19-2	9/30/2021	04/23/2020 - 07/29/2020
35	NP Thyroid® 90mg Tablets	42192-331-01	M331K19-6	9/30/2021	06/11/2020 - 07/08/2020