Chris,

On Tuesday, July 7, 2015, ODGR received your request to review one (1) procurement quota increase application from Aurolife Pharma LLC including Aurolife Pharma LLC Manufacturer and Aurobindo Pharma USA, Inc. Distributor who distributes to pending administrative/legal actions against these applicants and to advise ODEQ of the findings.

ODGR conducted reviews of (NADDIS, CSA, etc.), as well as surveyed the responsible field offices for their input and recommendations. Provided below are the results and recommendations.

**QUOTA APPLICANTS WITH NO ADVERSE OR DEROGATORY INFORMATION:**

- Aurolife Pharma LLC
- Aurolife Pharma LLC (Packager)

Per consultation with the field offices, DEA does not have sufficient grounds to limit, restrict, or deny quota requests from the Aurolife Pharma LLC including Aurolife Pharma LLC Manufacturer and Aurobindo Pharma USA, Inc. Distributor.

Based on the above findings, it is recommended that the increased amounts be reviewed to determine if they are warranted.
Based on this information, ODGR suggests that you proceed with the completion of the quota applications.
Memorandum

Subject
AUROLIFE PHARMA LLC
2015 Procurement Quota Increase Request
Hydrocodone
(DFN: 630-08.2)

Date
7/2/2015

To
Cathy Gallagher
Chief
Regulatory Section
Office of Diversion Control

From
Christine A. Sannerud, Ph.D.
Chief
UN Reporting and Quota Section
Office of Diversion Control

Background:
As a result of the recent increase in the diversion and abuse of hydrocodone, ODQ requests that ODG review the attached application and determine the legitimacy of the applicant’s customers. The application enclosed contains year to date sales (broken out by customer) for 2015 as provided by the registrant.

ODQ requests that ODG review and provide written comments to on the applicant’s enclosed customer list. Specifically, ODQ requests information on whether the applicant’s customers are currently under investigation or are the subject of an order to show cause or immediate suspension order. The sales made to such customers will be considered by ODQ when establishing/revising the applicant’s quota allocation for hydrocodone.

Please feel free to contact me if I can provide further assistance in this matter.
Drug Enforcement Administration
EXECUTIVE SECRETARIAT
CONTROL SHEET

REG NO: [bX7XE]

AUTHOR: Sannenid, Christine A
Chief
ODQ

DOC DATE: 7/6/2015

DATE RECEIVED: 

LOCATION: ODQ

DATE DUE: 07/16/2015

DATE CLOSED: 

SECURITY: A-AES

CREATED BY: 7/6/2015

MODIFIED BY: 7/5/2015

CATEGORIES:

DOC TYPE:

ABSTRACT: Auroxone Pharma, LLC 
2015 Procurement Quota Increase Request for hydrocodone.

SIGNATURE: ODGR/Regulatory Unit Response letter.

NOTES: FYI - INFO

COPIES:

FOLDER PRIORITY: High Priority

Assignments

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<th>Delegator</th>
<th>Status</th>
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7/9/2015 10:09:07 AM

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Drug Enforcement Administration

EXECUTIVE SECRETARIAT

CONTROL SHEET

REG NO: (b)(7)(E)

AUTHOR: Sannerud, Christine A
Chief
O:Q

DOC DATE: 7/6/2015

DATE RECEIVED: 7/6/2015

LOCATION: OOFQ

DATE DUE: 07/14/2015

DATE CLOSED: 7/6/2015

TO:

DATE RECEIVED: 07/14/2015

DATE CLOSED: 7/6/2015

SECURITY: A-ALS

CREATED BY: (b)(6);(b)(7)(C)

MODIFIED BY: 7/6/2015

DOC CATEGORIES:

DOC TYPE:

ABSTRACT: Aurotale Pharma, LLC 2015 Procurement Quota Increase Request for hydrocodone.

SIGNATURE: ODGR/Regulatory Unit Response letter.

NOTES: FYI - INFO

COPIES: FOLDER PRIORITY: High Priority

Assignments

Action Officer Delegator Status Date Assigned Date Due Closed Security

Recommendation and Comments

ODG [b](6);(b)(7)(C) Closed 7/6/2015 07/14/2015 7/6/2015 A-ALS

Requested Activity:

Reassgn [b](0);(b)(7)(C) Open 7/6/2015 07/20/2015 A-ALS

Requested Activity: Sending to ODGH [b](5);(b)(7)(C) on 7/8/2015

7/6/2015 12:39:18 PM

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**Reg No:** (b)(7)(E)

**Author:** Sannerud, Christine A  
**Addressed To:**

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**Date Sent:**

**Response:**

**Security:** A-AES  
**Abstract:** Aurolife Pharma, LLC  
(b)(4),(b)(7)(E)  
2015 Procurement Quota Increase Request for hydrocodone.

**Signature:** From ODG Response letter

**Doc Categories:**  
**Doc Types:**

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**Action:** Recommendation and Comments  
**Requested Activity:**  
**Response Notes:**