

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 6751 Steger Drive Cincinnati, OH 45237-3097 (513) 679-2700 Fax: (513) 679-2772	DATE(S) OF INSPECTION 8/5/2019-8/9/2019
	FEI NUMBER 3006316363

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
John Stubenrauch, Executive Director & General Manager

FIRM NAME Amylin Ohio LLC	STREET ADDRESS 8814 Trade Port Dr
------------------------------	--------------------------------------

CITY, STATE, ZIP CODE, COUNTRY West Chester, OH 45011-8661	TYPE ESTABLISHMENT INSPECTED Sterile Drug Manufacturer
---	---

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

**DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:
PRODUCTION SYSTEM**

OBSERVATION 1

Rejected in-process materials are not identified and controlled under a quarantine system to prevent their use in manufacturing or processing operations for which they are unsuitable.

Specifically,

On 08/07/2019, during packaging for Fasenra™ APFS commercial lot number LK0100, an unscheduled event occurred at the beginning of the run involving an equipment jam with a tray(s) of pre-filled glass syringes on the (b) (4). These impacted syringes were (b) (4).

(b) (4). According to a technician working on the line, syringes are (b) (4) on the Fasenra™ Assembler packaging line. Additionally, this unscheduled event was not documented in the executed batch record under section 11.3.(b) (4). Due to lack of documentation, the time and relevant information surrounding the unscheduled event are unknown. To date, your firm has produced (b) commercially packaged lots of Fasenra™ APFS ((lots for the US market), (lots utilizing the (b) (4).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Lauren N Howard, Investigator Teresa K Kastner, Investigator Richard T Riggie, Investigator	Lauren N Howard Investigator Signed By: Lauren N. Howard-S Date Signed: 08-09-2019 10:55:02 X	DATE ISSUED 8/9/2019

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 6751 Steger Drive Cincinnati, OH 45237-3097 (513) 679-2700 Fax: (513) 679-2772	DATE(S) OF INSPECTION 8/5/2019-8/9/2019
	FEI NUMBER 3006316363

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
John Stubenrauch, Executive Director & General Manager

FIRM NAME Amylin Ohio LLC	STREET ADDRESS 8814 Trade Port Dr
CITY, STATE, ZIP CODE, COUNTRY West Chester, OH 45011-8661	TYPE ESTABLISHMENT INSPECTED Sterile Drug Manufacturer

OBSERVATION 2

Records do not include the disposition of rejected components, drug product containers, closures and labeling.

Specifically,

During packaging validation of Fasenra™ AutoInjector, your firm aborted lot number (b) (4). According to your firm's Compliance and Quality Systems Director, the finished goods (approximately (b) (4)) were scrapped. However, your firm was unable to produce documentation showing traceability or disposition of the finished goods.

LABORATORY SYSTEM

OBSERVATION 3

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

Your firm failed to investigate the (b) (4) illustrated in **Table 1** below on three Fasenra™ AutoInjector batches. These batches were used in the packaging validation for this drug product.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Lauren N Howard, Investigator Teresa K Kastner, Investigator Richard T Riggie, Investigator	Lauren N Howard Investigator Signed By: Lauren N. Howard -S Date Signed: 08-09-2019 10:55:02 X	DATE ISSUED 8/9/2019

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 6751 Steger Drive Cincinnati, OH 45237-3097 (513) 679-2700 Fax: (513) 679-2772	DATE(S) OF INSPECTION 8/5/2019-8/9/2019
	FEI NUMBER 3006316363

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
John Stubenrauch, Executive Director & General Manager

FIRM NAME Amylin Ohio LLC	STREET ADDRESS 8814 Trade Port Dr
CITY, STATE, ZIP CODE, COUNTRY West Chester, OH 45011-8661	TYPE ESTABLISHMENT INSPECTED Sterile Drug Manufacturer

Table 1: PV Lots with Low Yield Results

Run Number	Lot Number	Percent Yield Result
1	JP2044	(b) (4)
2	JP2060	
3	JP2061	

Additionally, your firm added a fourth batch to the packaging validation, batch number KL0202, and removed the percent yield specification for this batch without justification.

X Richard T Riggie
Investigator
Signed By: Richard T. Riggie -S
Date Signed: 08-09-2019 10:55:34

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Lauren N Howard, Investigator Teresa K Kastner, Investigator Richard T Riggie, Investigator	Lauren N Howard Investigator Signed By: Lauren N. Howard -S Date Signed: 08-09-2019 10:55:02 X	DATE ISSUED 8/9/2019

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 6751 Steger Drive Cincinnati, OH 45237-3097 (513) 679-2700 Fax: (513) 679-2772	DATE(S) OF INSPECTION 8/5/2019-8/9/2019
	FEI NUMBER 3006316363

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
 John Stubenrauch, Executive Director & General Manager

FIRM NAME Amylin Ohio LLC	STREET ADDRESS 8814 Trade Port Dr
------------------------------	--------------------------------------

CITY, STATE, ZIP CODE, COUNTRY West Chester, OH 45011-8661	TYPE ESTABLISHMENT INSPECTED Sterile Drug Manufacturer
---	---

Annotations to Observations

Observation 1:

Observation 2:

Observation 3:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Lauren N Howard, Investigator Teresa K Kastner, Investigator Richard T Riggie, Investigator	DATE ISSUED 8/9/2019
	Lauren N Howard Investigator Signed By: Lauren N. Howard -S Date Signed: 08-09-2019 10:55:02 X _____	

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."