

Tischler, Tarin

From: Tischler, Tarin
Sent: Thursday, July 28, 2022 5:51 PM
To: Tiffany.Holmes@tevapharm.com
Cc: Stark, Justin
Subject: Actavis Laboratories FL Inc (EPAID: FLR000071787) Exit Interview

Ms. Holmes,

This email serves as an exit interview for the Florida Department of Environmental Protection compliance evaluation inspection of Actavis Laboratories FL Inc on 7/27/2022. Thank you for your cooperation with our inspection procedures. As Mr. Gil may have mentioned, additional documentation is being requested before returning your facility to compliance.

Please submit the following documentation by **08/15/2022**:

1. Waste profile(s) for sludge generated in the waste water treatment plant

Please submit all waste profiles for sludge generated in the waste water treatment system for Department review.

2. Documentation of weekly inspections of hazardous waste containers

Per 40 CFR 262.17(a)(1)(v):

At least weekly, the large quantity generator must inspect central accumulation areas. The large quantity generator must look for leaking containers and for deterioration of containers caused by corrosion or other factors. See [paragraph \(a\)\(1\)\(ii\)](#) of this section for remedial action required if deterioration or leaks are detected.

Please submit documentation of weekly inspections of hazardous waste containers in the central accumulation area for the past 3 months.

3. Written job descriptions for positions at the facility related to hazardous waste management

Per 40 CFR 262.17(a)(7)(iv), *The large quantity generator must maintain the following documents and records at the facility:*

(A) The job title for each position at the facility related to hazardous waste management, and the name of the employee filling each job;

(B) A written job description for each position listed under paragraph (a)(7)(iv)(A) of this section. This description may be consistent in its degree of specificity with descriptions for other similar positions in the same company location or bargaining unit, but must include the requisite skill, education, or other qualifications, and duties of facility personnel assigned to each position;

(C) A written description of the type and amount of both introductory and continuing training that will be given to each person filling a position listed under paragraph (a)(7)(iv)(A) of this section;

(D) Records that document that the training or job experience, required under paragraphs (a)(7)(i), (ii), and (iii) of this section, has been given to, and completed by, facility personnel.

Please submit, as described above, a written job description for each position at the facility related to hazardous waste management. This should include the job title, name of person filling each position, and the amount of training required. Please maintain these records at the facility in the future.

4. Photo documentation of the satellite accumulation and central accumulation containers labeled with an indication of the hazards of its contents

Per 40 CFR 262.17(a)(5)(B), a large quantity generator must mark or label its container with the following:

An indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (i.e., ignitable, corrosive, reactive, toxic); hazard communication consistent with the Department of Transportation requirements at [49 CFR part 172 subpart E](#) (labeling) or subpart F (placarding); a hazard statement or pictogram consistent with the Occupational Safety and Health Administration Hazard Communication Standard at [29 CFR 1910.1200](#); or a chemical hazard label consistent with the National Fire Protection Association code 704)

Per 40 CFR 262.15(a)(5)(ii) satellite accumulation area regulations for small and large quantity generators, a generator must mark or label its containers with the following:

An indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (i.e., ignitable, corrosive, reactive, toxic); hazard communication consistent with the Department of Transportation requirements at [49 CFR part 172 subpart E](#) (labeling) or subpart F (placarding); a hazard statement or pictogram consistent with the Occupational Safety and Health Administration Hazard Communication Standard at [29 CFR 1910.1200](#); or a chemical hazard label consistent with the National Fire Protection Association code 704).

Please submit photo documentation of all satellite and central accumulation containers labeled with an indication of the hazards of their contents. As stated in the regulations above, this may include the words ignitable, corrosive, reactive, or toxic written on the label, or the DOT regulated placarding stickers.

5. Photo documentation of the 55-gallon container used for central accumulation of alcohol waste labeled with an accumulation date

Per 40 CFR 262.15(a):

A generator may accumulate as much as 55 gallons of non-acute hazardous waste and/or either one quart of liquid acute hazardous waste listed in [§ 261.31](#) or [§ 261.33\(e\) of this chapter](#) or 1 kg (2.2 lbs) of solid acute hazardous waste listed in [§ 261.31](#) or [§ 261.33\(e\) of this chapter](#) in containers at or near any point of generation where wastes initially accumulate which is under the control of the operator of the process generating the waste, without a permit or interim status and without complying with the requirements of [parts 124, 264 through 267, and 270 of this chapter](#), provided that all of the conditions for exemption in this section are met. A generator may comply with the conditions for exemption in this section instead of complying with the conditions for exemption in [§ 262.16\(b\)](#) or [§ 262.17\(a\)](#), except as required in [§ 262.15\(a\)\(7\)](#) and [\(8\)](#).

At the time of the inspection, a 55-gallon drum was being used to accumulate alcohol waste from satellite containers in the QC/QA laboratory area. This container does not meet the definition of a satellite container as it is not placed at or near the point of generation of the waste, and it is not under control of the operator of the process generating the waste. The alcohol is generated in separate laboratory rooms by laboratory personnel and placed in acceptable satellite containers before being moved to this container. This container is a central accumulation container and should be labeled with the words "Hazardous waste," an indication of the hazards of its contents, and the date upon which each period of accumulation begins clearly visible for inspection on each container.

6. A copy of your facility's 2021 Biennial Report

Please submit a copy of your facility's most recent (2021) Biennial Report for Department review.

7. A copy of your facility's contingency plan updated to include evacuation routes and updated emergency coordinators

Per 40 CFR 262.261(f) Content of the contingency plan:

The plan must include an evacuation plan for generator personnel where there is a possibility that evacuation could be necessary. This plan must describe signal(s) to be used to begin evacuation, evacuation routes, and alternate evacuation routes (in cases where the primary routes could be blocked by releases of hazardous waste or fires).

At the time of the inspection, Actavis's contingency plan referenced that evacuation routes are posted throughout the facility. These routes should be included in the contingency plan itself describing the information listed above. The alternate emergency coordinator was also out of date as Haley Laing is no longer employed at Actavis. Please add these updates to your contingency plan and submit an updated copy of the plan to the Department.

8. A copy of your facility's Quick Reference Guide of your contingency plan and documentation of updated notification with local authorities

Per 40 CFR 262.262(b):

A large quantity generator that first becomes subject to these provisions after May 30, 2017 or a large quantity generator that is otherwise amending its contingency plan must at that time submit a quick reference guide of the contingency plan to the local emergency responders identified at [paragraph \(a\)](#) of this section or, as appropriate, the Local Emergency Planning Committee. The quick reference guide must include the following elements:

- (1) The types/names of hazardous wastes in layman's terms and the associated hazard associated with each hazardous waste present at any one time (e.g., toxic paint wastes, spent ignitable solvent, corrosive acid);*
- (2) The estimated maximum amount of each hazardous waste that may be present at any one time;*
- (3) The identification of any hazardous wastes where exposure would require unique or special treatment by medical or hospital staff;*
- (4) A map of the facility showing where hazardous wastes are generated, accumulated and treated and routes for accessing these wastes;*
- (5) A street map of the facility in relation to surrounding businesses, schools and residential areas to understand how best to get to the facility and also evacuate citizens and workers;*
- (6) The locations of water supply (e.g., fire hydrant and its flow rate);*
- (7) The identification of on-site notification systems (e.g., a fire alarm that rings off site, smoke alarms); and*
- (8) The name of the emergency coordinator(s) and 7/24-hour emergency telephone number(s) or, in the case of a facility where an emergency coordinator is continuously on duty, the emergency telephone number for the emergency coordinator.*

Please submit a copy of a quick reference guide of the contingency plan to local authorities with the information above to make them aware of the required updates, and send documentation of this notification and a copy of the quick reference guide to the Department.

Please submit the above documentation by **8/15/2022**. If you have any questions or concerns regarding the required documentation, please do not hesitate to reach out to me.

Thank you,



Tarin Tischler

Environmental Specialist II

Florida Department of Environmental Protection
Southeast District – West Palm Beach
3301 Gun Club Road, MSC 7210-1
West Palm Beach, FL 33406
Tarin.Tischler@FloridaDEP.gov
Office: 561.681.6680