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ENGINEERING EVALUATION / FACT SHEET

BACKGROUND INFORMATION

Application No.:	R13-2068U
Plant ID No.:	061-00033
Applicant:	Mylan Pharmaceuticals Inc.
Facility Name:	Chestnut Ridge Facility
Location:	Monongalia County
SIC/NAICS Code:	2834/325412
Application Type:	Modification
Received Date:	July 27, 2017
Engineer Assigned:	Joe Kessler
Fee Amount:	$1,000
Date Received:	August 2, 2017
Complete Date:	August 24, 2017
Due Date:	November 22, 2017
Applicant Ad Date:	August 2, 2017
Newspaper:	*The Dominion Post*
UTM's:	Easting: 589.6 km Northing: 4,390.1 km Zone: 17
Latitude/Longitude:	39.65923/-79.95824
Description:	Modification to authorize the use of VOC-containing solvents in an additional fluid bed (583) and an increase in the solvent use in various coating pans (241, 242, 244, 245, 246, 247).

Mylan Pharmaceuticals Inc. (Mylan) is a batch pharmaceutical manufacturing company that purchases raw materials from various suppliers and produces solid-dose pharmaceuticals. The Chestnut Ridge Facility was originally constructed in the 1960's and became a grandfathered source when the minor source program was promulgated in 1974. The facility has received, however, numerous 45CSR13 permits for expansions and modifications since that time.

Significantly, under permit R13-2068K, issued on January 5, 2010, Mylan received authorization to install a regenerative thermal oxidizer (RTO) to control VOC emissions from various processes at the plant. They stated, at the time, that their goal was to bring potential facility-wide VOC emissions to below 100 tons per year (TPY). As of yet, however, Mylan has not taken credit for all the potential reductions of VOC emissions associated with the installation of the RTO.

Since the issuance of R13-2068K, Mylan's Chestnut Ridge facility has been the subject of the following permitting actions:

- On May 4, 2010, Mylan withdrew a permit application that had proposed to increase fluid bed VOC emissions to account for change in product formulations. After looking at product forecasts, Mylan decided this modification was unnecessary;

- On November 3, 2010, Mylan was issued R13-2068M to authorize installation and operation of an additional coating pan (245);

- On January 5, 2011, Mylan was issued R13-2068N as a Class II Administrative Update to authorize Mylan to take credit for VOC destruction in the RTO for Fluid Beds 534, 538, 572, 574 – 578, and 580 and to remove authorization for use of a Catalytic Oxidizer;

- On September 14, 2011, Mylan was issued R13-2068O for the: (1) Increase of the permitted capacity of various fluid beds, (2) Addition of an absorber to the permit, (3) Controlling of two fluid beds (573, 579) with the absorber, (4) Controlling of two coating pans (244, 245) with the RTO, and (5) Controlling of previously grandfathered oven dryers with the RTO;

- On August 12, 2013, Mylan was issued R13-2068P as a Class II Administrative Update for various equipment replacements and the addition of an Oven Dryer and a Coating line;

- On September 29, 2014, Mylan was issued R13-2068Q as a Class II Administrative Update for installation of a new roof mounted cartridge collector to control particulate matter emissions generated in fifteen (15) existing production rooms;

- On November 3, 2015, Mylan was issued R13-2068R for the installation of a new coating pan (246) and associated dust collector (CC 246);

- On October 28, 2016, Mylan was issued R13-2068S as a Class II Administrative Update for installation of: (1) a new fluid bed (583, 583) and associated cartridge collector (CC 10024247), (2) a new 6.0 mmBtu/hr boiler (016, 016), and (3) the replacement of three old cartridge collectors; and

- On April 17, 2017, Mylan was issued R13-2068T as a Class II Administrative Update for the addition of one (1) coating pan (247) and an associated dust collector (CC 10024526) and the addition of one (1) additional cartridge-type dust collector (CC 10030432) to control particulate matter emissions from specific production rooms (Rooms 74-101 to 74-110).

DESCRIPTION OF PROCESS/MODIFICATIONS

Existing Facility

Mylan Pharmaceuticals Inc. (Mylan) is a batch pharmaceutical manufacturing company that purchases raw materials from various suppliers and produces solid-dose pharmaceuticals. The

Chestnut Ridge Facility was originally constructed in the 1960's and became a grandfathered source when the minor source program was promulgated in 1974. The facility has received, however, 45CSR13 permits for expansions and modifications since that time.

The manufacturing process is accomplished by weighing, blending, granulating, formulating, and packaging operations. Air emissions are produced by boiler exhaust, loss of pharmaceutical ingredients as particulate matter during the manufacturing processes, and the release/loss of VOC-containing solvents during manufacturing processes. Existing emission controls include wet scrubbers, cartridge-type dust collectors, an absorber, and an RTO. Mylan primarily uses the following production equipment and emission controls in the manufacturing process:

Fluid Beds

Fluid beds are used to mix, compound, formulate and/or dry powders or particles utilizing water and/or non-HAP organic solvents depending on the product and formulation. The fluid beds are equipped with integral dust collection filters (cartridge collectors) capturing the powders within the fluid bed. The exhaust of each fluid bed are also controlled by a cartridge collector filter system for particulate matter. Nineteen (19) fluid beds are currently permitted. At this time, Mylan has taken credit (and permitted) for control of nine (9) fluid beds (534, 538, 572, 574-578, 580) with the RTO and two (2) with the absorber (573, 579).

Coating Pans

Coating pans are used to coat formulated tablets with a solution containing water and/or non-HAP solvents. Dry materials are loaded into the coating pan and then solutions are sprayed onto the materials at varying rates depending upon the product being manufactured. Seven (7) coating pans are currently permitted. At this time, Mylan has taken credit (and permitted) for control of four (4) coating pans (244, 245, 246, 247) with the RTO.

Oven Dryers

Three existing oven dryers (260, 261, and 264) are used for drying solvent from product that has been granulated using solvent and/or water in a separate mixer operation. Wet product is placed on trays and racks which are placed inside the ovens for a specific amount of time. The heat of the ovens drives off the volatiles which are sent to the RTO for control.

Regenerative Thermal Oxidation

The RTO has been installed at the Mylan facility to oxidize solvent emissions from selected VOC sources. Exhaust from sources selected for control by the RTO are ducted to a main line which conveys the air stream to the RTO with a combined burner rating not to exceed 16.00 million BTU/hr. The air stream passes through heat recovery media prior to entering the burner chamber where oxidation of the VOCs occurs. The combustion gases exit the burner chamber through the additional heat exchange media prior to exiting the unit through the stack. The manufacturer guarantees a VOC destruction efficiency of at least 99% (Mylan conservatively estimates a minimum 98% VOC destruction efficiency for emissions estimates).

Absorber

The Absorber is a typical packed bed-design that uses fresh water (maximum design flow rate of 100 gal/min) to control ethanol and/or isopropyl alcohol solvent emissions from Fluid Beds 573 and 579. The VOC control efficiency from use of the absorber is 95%.

Rotoclones & Cartridge Collectors

Rotoclones are control devices (using internal water sprays) that are used to control particulate matter emissions from general exhaust fans servicing production rooms. Cartridge collectors are fabric filters used to control particulate matter from individual fluid beds and coating pans.

Proposed Modifications

Mylan is now proposing the use of VOC-containing solvents in an additional fluid bed (583) and an increase in the existing solvent use in various coating pans (241, 242, 244, 245, 246, 247). Previously, fluid bed 583 was not authorized to use VOC-containing solvents and the coating pans were limited to an aggregate limit of 5.0 tons-VOC/year. Mylan is requesting the coating pan VOC limit be increased to 10.0 tons-VOC/year. Mylan is not requesting any increase in the aggregate VOC emissions limit from the fluid beds. Fluid bed 583 will not have the capability to exhaust to the RTO and will vent emissions directly to the atmosphere.

Additionally, Mylan has requested alternate visible emissions monitoring language for the fluid beds and coating pans to account for months when specific units do not operate. The revised language can be reviewed under 6.2.1 and 8.2.1 of the draft permit.

SITE INSPECTION

Due to the nature of the proposed changes, the writer did not conduct a site inspection. According to information in the DAQ database, the last “full on-site” inspection occurred on September 29, 2015 by Ms. Rebecca Johnson of the Compliance/Enforcement Section. The facility was given a status code of "30 - In Compliance" as a result of the inspection.

REVIEW OF APPLICANT’S EMISSIONS ESTIMATE

The following will review Mylan’s methodology of calculating emissions from those units that are added or modified as a result of this permitting action.

Fluid Beds

VOC emissions from the fluid beds are calculated by using a material balance methodology. This is accomplished on a hourly basis by calculating the maximum pounds of VOCs used in each fluid bed per hour, based on the design capacity of the spray guns and the VOC content of the solvents (assumed to be worst case 100% VOC). Due to the variation in VOC content of the many

different solvents used, annual emissions are arbitrarily set at annual aggregate level based on "product type and forecast. . . [n]ot based on hourly rate." Currently, the aggregate annual VOC emission rate of all the fluid beds is 74.00 tons/year (TPY).

Mylan is proposing to process VOC-containing solvents in an existing fluid bed (583) that was previously not authorized to do so. The fluid bed will not have the capability to vent to the RTO and will vent directly to the atmosphere. When exhausting straight to atmosphere, the following calculation applies:

Eq. 1: E_{FB} (lb-VOC/hr) = [Spray Gun Capacity (kg-solvent/hour)] * [VOC Content of Solvent (lb-VOC/kg-solvent)]

E_{FB} (lb-VOC/hr) = [240 kg/hour] * [2.205 lb-VOC/kg-solvent)]

E_{FB} (lb-VOC/hr) = 529.20 lb-VOC/hour

Again, due to the variation in VOC content of the many different solvents used, the annual VOC emissions are not based on a permitted hours of operation, throughput, or batches per year. The annual emissions are set arbitrarily for all fluid beds and Mylan shows compliance with the limit based on a sophisticated actual emissions monitoring and recording procedure. As noted above, however, Mylan did not request any increase in the aggregate annual VOC emission rate for the fluid beds to accommodate the modification evaluated herein. It is noted that as there is no limit on the number of fluid beds that may use VOC-containing solvents at any one time, the proposed new authorization to use VOC-containing solvents in fluid bed 583 will potentially increase the facility-wide worst case hourly emission rate by 529.20 lbs/hr.

Coating Pans

VOC emissions from the coating pans are calculated by using a material balance methodology. This is accomplished on a hourly basis by calculating the maximum pounds of VOCs used in each coating pan based on the design capacity of the spray guns and the VOC content of the solvents. Due to the variation in VOC content of the many different solvents used, annual emissions are arbitrarily set at annual aggregate level based on "product type and forecast. . . [n]ot based on hourly rate." Annual emissions from all coating pans are currently set at an aggregate of 5.0 TPY. The hourly VOC emission calculation is given below when venting directly to the atmosphere. When controlled by the RTO, the VOC emissions would be reduced by 98%.

Eq. 2: E_{CP} (lb-VOC/hr) = [Spray Gun Capacity (grams/hour)] * [VOC Content of Solvent (lb-VOC/gram)]

E_{CP} (lb-VOC/hr) = [180,000 grams/hour] * [0.002205 lb-VOC/gram]

E_{CP} (lb-VOC/hr) = 396.90 lb-VOC/hr

Again, due to the variation in VOC content of the many different solvents used, the annual VOC emissions are not based on a permitted hours of operation, throughput, or batches per year. The annual emissions are set arbitrarily for all fluid beds and Mylan shows compliance with the limit based on a sophisticated actual emissions monitoring and recording procedure. Due to expected increases in VOC-solvents used, Mylan is requesting an increase in the annual aggregate VOC emissions limit from the coating pans from 5.0 to 10.0 TPY.

Emissions Summary

Based on the changes evaluated herein, the new facility-wide annual PTE of the Morgantown facility is given in the following table:

Table 1: Post-Modification Facility-Wide Annual PTE

Permit	NO_x	CO	VOCs	SO_2	PM[(1)]	HAPs
R13-2068T[(2)]	67.08	87.50	141.96	0.62	76.04	24.40
2068U Change	*0.00*	*0.00*	*5.00*	*0.00*	*0.00*	*0.00*
R13-2068U	**67.08**	**87.50**	**146.96**	**0.62**	**76.04**	**24.40**

(1) All particulate matter emitted is assumed to be $PM_{2.5}$ or less and includes condensables.
(2) Existing PTE calculated from data in R13-2068T Engineering Evaluations/Fact Sheet.

REGULATORY APPLICABILITY

This section will address the potential regulatory applicability/non-applicability of substantive state and federal air quality rules relevant to this permitting action.

45CSR13: Permits for Construction, Modification, Relocation and Operation of Stationary Sources of Air Pollutants, Notification Requirements, Administrative Updates, Temporary Permits, General Permits, and Procedures for Evaluation

The proposed changes to the Chestnut Ridge Facility will have the potential to increase a regulated pollutant above 144 lbs/day (VOC emissions from the fluid bed that would now be authorized to use VOC-containing solvents). This potential increase, pursuant to §45-13-2.17, defines the change as a "modification" under 45CSR13. Pursuant to §45-13-5.1, "[n]o person shall cause, suffer, allow or permit the construction, modification, relocation and operation of any stationary source to be commenced without . . . obtaining a permit to construct." Therefore, Dominion is required to obtain a permit under 45CSR13 for the modification of the facility.

Therefore, as required under §45-13-8.3 ("Notice Level A"), Mylan placed a Class I legal advertisement in a "newspaper of general circulation in the area where the source is . . . located." The ad ran on August 2, 2017 in *The Dominion Post*. Mylan provided verification that the legal advertisement ran on August 10, 2017.

45CSR14: Permits for Construction and Major Modification of Major Stationary Sources of Air Pollution for the Prevention of Significant Deterioration - (NON APPLICABILITY)

Mylan's Chestnut Ridge Facility is located in Monongalia County, WV. Monongalia County is classified as "in attainment" with all National Ambient Air Quality Standards. Therefore, as the facility is a "listed source" under §45-14-2.43 (Chemical Process Plant - first two digits of the SIC Code are 28), the individual major source applicability threshold for all NSR pollutants is 100 TPY. As the facility-wide VOC PTE of the existing facility is greater than 100 TPY, the facility is defined as a "major stationary source" under 45CSR14.

Therefore, to determine if the proposed changes are defined as a "major modification" to the Chestnut Ridge Facility, pursuant to §45-14-3.4(a), the project is examined under a two-step applicability test: "[A] project is a major modification for a regulated NSR pollutant if it causes two types of emissions increases -- a significant emissions increase (as defined in subsection [§45-14-2.75]), and a significant net emissions increase (as defined in subsections [§45-14-2.46] and [§45-14-2.74]). The proposed project is not a major modification if it does not cause a significant emissions increase. If the proposed project causes a significant emissions increase, then the project is a major modification only if it also results in a significant net emissions increase."

Therefore, for the proposed changes to meet the definition of a major modification, the increase in use of VOC-containing solvents in the coating pans must alone result in a significant emissions increase. The methodology for calculating the emissions increase under the first step is given under Sections §45-14-3.4(b), 3.4(c), 3.4(d) and 3.4(f). The substantive language relevant to the changes evaluated herein is given below:

> **[§45-14-3.4(b)]**
> The procedure for calculating (before beginning actual construction) whether a significant emissions increase (i.e., the first step of the process) will occur depends upon the type of emissions units being modified, according to subdivisions 3.4.c through 3.4.f.
>
> **[§45-14-3.4(c)]**
> Actual-to-projected-actual applicability test for projects that only involve existing emissions units. -- A significant emissions increase of a regulated NSR pollutant is projected to occur if the sum of the difference between the projected actual emissions (as defined in subsection 2.63) and the baseline actual emissions (as defined in subdivisions 2.8.a and 2.8.b), for each existing emissions unit equals or exceeds the significant amount for that pollutant (as defined in subsection 2.74).

Based on the total VOC PTE associated with the coating pans of 10 TPY, it is clear that any increase in actual VOC emissions from coating pans could not exceed the VOC significant emissions threshold under 2.74 of 40 TPY and, therefore, the proposed changes to the coating pans are not defined as a "major modification" under 45CSR14.

The new use of VOC-containing solvents in fluid bed 583 may be considered a “change in the method of operation” of the fluid beds - here considered as an aggregate emission unit - and, therefore, require a PSD applicability analysis. In this case, a qualitative PSD applicability analysis shows that, as Mylan is not requesting to increase the aggregate annual VOC limit for the fluid beds, this change could not be defined as a “major modification” under 45CSR14. This analysis is based on the procedure for calculating the actual-to-projected actual (as given under §45-14-2.63) emissions increase of the fluid beds. Specifically, under 2.63(a)(3), 45CSR14 states that the actual emissions increase shall exclude “that portion of the unit's emissions following the project that an existing unit could have accommodated during the consecutive 24-month period used to establish the baseline actual emissions . . .” It is clear that the existing fluid beds - here considered an aggregate emissions unit - could have accommodated any actual emissions increase from the fluid beds (note again that the existing VOC emissions limit for the fluid beds is not being increased).

It is important to note that the DAQ does not necessarily consider the changes evaluated herein to be part of any other project that would necessitate aggregating multiple project emissions together

to compare to the PSD applicability thresholds. However, Mylan did include in the permit application a summary of changes made over the last six (6) years that included other changes in VOC emissions. This analysis shows that the last change at the facility that affected annual VOC emissions occurred in July 2013 and ultimately reduced potential VOC emissions by 20 TPY.

45CSR30: Requirements for Operating Permits

45CSR30 provides for the establishment of a comprehensive air quality permitting system consistent with the requirements of Title V of the Clean Air Act. The Mylan Chestnut Ridge facility, defined under Title V as a "major source," was last issued a Title V permit on March 9, 2017. Changes authorized by the proposed permit must also be incorporated into the facility's Title V operating permit. Commencement of the operations authorized by this permit (which is the operation of the plant) shall be determined by the appropriate timing limitations associated with Title V permit revisions per 45CSR30.

TOXICITY ANALYSIS OF NON-CRITERIA REGULATED POLLUTANTS

No increase in non-criteria regulated pollutants will result from the changes evaluated herein.

AIR QUALITY IMPACT ANALYSIS

The proposed changes do not meet the definition of a "major modification" pursuant to 45CSR14 and, therefore, an air quality impact (computer modeling) analysis was not required. Additionally, based on the nature of the proposed changes, modeling was not required under 45CSR13, Section 7.

MONITORING, COMPLIANCE DEMONSTRATIONS, RECORD-KEEPING, AND REPORTING REQUIREMENTS

No substantive changes to the existing monitoring, compliance demonstrations, reporting or record-keeping requirements were made as part of this permitting process.

PERFORMANCE TESTING OF OPERATIONS

No new performance tests were required as a result of the changes permitted herein. The coating pans are subject to the general testing requirements given under 3.3 of the permit.

CHANGES TO PERMIT R13-2068T

The substantive changes made to Permit R13-2068T are as follows:

- The visible emission requirements under 6.2.1. and 8.2.1. were revised;

- Language under 8.1.6(h) limiting coating pan solvent use to any five (5) coating pans at a time was removed; and

- The aggregate coating pan VOC limit under 8.1.5. of the permit was increased to 10 TPY.

RECOMMENDATION TO DIRECTOR

The information provided in the permit application indicates that compliance with all applicable state and federal air quality regulations will be achieved. Therefore, I recommend to the Director the issuance of Permit Number R13-2068U to Mylan for the above discussed changes to the Chestnut Ridge Facility located in Morgantown, Monongalia County, WV.

Joe Kessler, PE
Engineer

Date