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**west virginia** department of environmental protection

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**ENGINEERING EVALUATION / FACT SHEET**

**BACKGROUND INFORMATION**

Application No.: R13-2068O  
Plant ID No.: 061-00033  
Applicant: Mylan Pharmaceuticals Inc.  
Facility Name: Chestnut Ridge Facility  
Location: Monongalia County  
NAICS Code: 325412  
Application Type: Modification  
Received Date: June 13, 2011  
Engineer Assigned: Joe Kessler  
Fee Amount: \$1,000  
Date Received: June 21, 2011  
Complete Date: July 13, 2011  
Due Date: October 11, 2011  
Applicant Ad Date: June 17, 2011  
Newspaper: *Dominion Post*  
UTM's: Easting: 589.6 km Northing: 4,390.1 km Zone: 17  
Description: This modification addresses the following: (1) Increase the permitted capacity of various fluid beds, (2) Take credit for control of two fluid beds (573, 579) with an absorber, (3) Take credit for control of previously grandfathered ovens with the RTO, (4) Addition of an Absorber to the permit, (5) Take credit for control of two coating pans (244, 245) with the RTO.

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.

Mylan, under permit R13-2068K, issued on January 5, 2010, received authorization to install regenerative thermal oxidation (RTO) and Catalytic Oxidation (CO) to control VOC emissions from various processes at the plant. They stated that their goal was to bring potential facility-wide VOC emissions to below 100 tons per year (TPY). At that time, however, Mylan did not take credit for the reduction of VOC emissions associated with the installation of the RTO. They planned to install the oxidizers and test them prior to taking credit for the VOC reductions. They did, however, under R13-2068K, permit the potential products of combustion from use of the oxidizers.

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.

### DESCRIPTION OF PROCESS/MODIFICATIONS

As noted above, Mylan is a batch pharmaceutical manufacturing company that purchases raw materials from various suppliers and produces solid-dose pharmaceuticals. This 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 manufacturing processes, and the release/loss of VOC-containing solvents during manufacturing processes. It is important to note that Mylan has eliminated all HAP-containing solvents from their processes. Existing emission controls include wet scrubbers, cartridge collectors and an RTO.

Four existing processes are of concern in this modification: fluid beds, coating pans, oven dryers (currently grandfathered) and the RTO. Mylan is also proposing the use of a new absorber for the control of VOCs from two fluid beds.

#### **Fluid Beds**

Fluid beds are used to mix, compound, formulate and/or dry powders or particles utilizing water and/or non-HAP solvents depending on the product and formulation. The fluid beds are equipped with integral dust collection filters capturing the powders within the fluid bed. The exhaust of each fluid bed is controlled by a cartridge collector filter system for particulate matter. Eighteen (18) fluid beds are currently authorized under R13-2068N. Mylan is now proposing to vent the solvent-laden exhaust from Fluid Beds 573 and 579, during the production of certain products, to the absorber for control of VOCs.

Additionally, Mylan is proposing to increase the aggregate dry material loading of the Fluid Beds from 154 kg/load (Fluid Beds 534, 536, 538, 572, 574, 575, 577, and 581) to 250 kg/load and from 550 kg/load (Fluid Beds 533, 535, 537, 571, 573, 576, 578, 579, 580, and 582) to 575 kg/load.

#### **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. Mylan's production formulations utilizing the coating pans have been water based since the voluntary elimination of methylene chloride over ten years ago. However, new technology is requiring Mylan to introduce solvents into the production coating process. Five (5) fluid beds are currently authorized under R13-2068N. At this time, Mylan is requesting a permit modification to take credit for control of two coating pans (244, 245) with the RTO.

### **Oven Dryers**

The four existing oven dryers (260-263) 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 either released directly to atmosphere, or as proposed by Mylan as part of this permitting action, 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. Mylan is requesting, in this permitting action, authorization to take credit for control of solvent emissions from, in addition to Fluid Beds 534, 538, 572, 574 – 578, and 580 as permitted under R13-2068N, coating pans 244 and 245 and from the Oven Dryers 260-263. Exhaust from these new sources will be ducted to a main line which will convey the air stream to the RTO with a combined burner rating not to exceed 16.00 million BTU/hr. The air stream will pass 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 heat exchange media prior to exiting the unit through the stack. The manufacturer guarantees a VOC destruction efficiency of at least 99% (Mylan is conservatively estimating a minimum 98% VOC destruction efficiency for the emissions estimate in this application).

### **Absorber**

Mylan is proposing, in the permitting action reviewed herein, to begin taking credit for the control of VOCs from Fluid Beds 573 and 579 in the Absorber. The Absorber is a typical packed bed-design that will use fresh water (maximum design flow rate of 100 gal/min) to control ethanol and/or isopropyl alcohol solvent emissions. Mylan has requested a permitted VOC control efficiency from use of the absorber of 95%.

### **SITE INSPECTION**

On November 4, 2009, the writer conducted a site inspection of Mylan's Chestnut Ridge facility. The primary contacts for the inspection were Mr. Craig Travis, Senior Manager Global Environmental Compliance and Mr. Dale Stemple, Executive Director Corporate Safety and Environmental Compliance and Global Security. After an initial discussion of permitting issues, the writer was given a tour of the major production areas of the facility including the fluid bed and coating pan areas and shown the proposed location of the RTO and catalytic oxidizer. Some observations from the inspection include:

- The Mylan facility is located in a heavily populated area off of Chestnut Ridge Road (Route 705) in Morgantown. It is closely bounded on all sides by other businesses and residential neighborhoods. There is a school and several hospitals near the location.
- The location of the RTO is on the west side of the facility. Exhaust from the fluid beds and coating pans will be ducted on the roof to the RTO. The stack of the RTO rises 20 feet above the roof level of the facility.
- The fluid beds/coating pans are variable, batch type processes. After each use the units must be stripped down and cleaned before the next batch is loaded. Additionally, due to the sizes and design of each fluid bed/coating pan, the units are limited to the range of products they can make. This greatly limits the number of fluid beds/coating pans that can be operating at any one time.
- No odor was noticed outside the facility and no opacity was visible at any time from any of the emission sources.

## REVIEW OF APPLICANT'S EMISSIONS ESTIMATE

The following will review the methodology of calculating emissions from those units that are 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 emission rate of all the fluid beds is 99.00 TPY. However, as a result of this permitting action, on October 1, 2011, the annual limit shall be reduced to 94.00 TPY.

Mylan has proposed the use of the RTO as a control for Fluid Beds 534, 538, 572, 574 – 578, and 580 for certain products and use of the Absorber as a control for Fluid Beds 573 and 579 for certain products. Example hourly emission calculations for a single fluid bed are given below:

When exhausting straight to atmosphere, the following calculation applies:

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

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

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

When exhaust from Fluid Beds 534, 538, 572, 574 – 578, and 580 are routed to the RTO (98% permitted control efficiency [9.1.5.]) for VOC control, the following calculation applies:

$$\text{Eq. 2: } E_{\text{FB}} (\text{lb-VOC/hr}) = [\text{Uncontrolled VOC Emission Rate (lb-VOC/hour)}] * [1 - ((\text{RTO VOC Destruction Efficiency } (\%)/100)]$$

$$E_{\text{FB}} (\text{lb-VOC/hr}) = [529.20 \text{ lb-VOC/hour}] * [0.02]$$

$$E_{\text{FB}} (\text{lb-VOC/hr}) = 10.59 \text{ lb-VOC/hour}$$

When exhaust from Fluid Beds 573 and 579 are routed to the Absorber (95% permitted control efficiency [11.1.4.]) for VOC control, the following calculation applies:

$$\text{Eq. 3: } E_{\text{FB}} (\text{lb-VOC/hr}) = [\text{Uncontrolled VOC Emission Rate (lb-VOC/hour)}] * [1 - ((\text{RTO VOC Destruction Efficiency } (\%)/100)]$$

$$E_{\text{FB}} (\text{lb-VOC/hr}) = [529.20 \text{ lb-VOC/hour}] * [0.05]$$

$$E_{\text{FB}} (\text{lb-VOC/hr}) = 26.46 \text{ lb-VOC/hour}$$

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 and Mylan shall show compliance with the limit based on a sophisticated actual emissions monitoring and recording procedure.

Particulate matter emissions from each fluid bed is based on the amount of dry material feed that is lost in the process (estimated to be 0.0005%) and that is not controlled by the cartridge collector (estimated at 95% efficient [6.1.6(c)]). Mylan also factors in an additional pre-control safety factor (they refer to it as an “upset/excursion” factor) of 2.4.

Maximum hourly emissions are based on the maximum dry material loading per load: proposed at 250 kg/load for Fluid Beds 534, 536, 538, 572, 574, 575, 577, and 581 and 575 kg/load for Fluid Beds 533, 535, 537, 571, 573, 576, 578, 579, 580, and 582. Annual particulate matter emissions are based on a maximum aggregate dry material loading throughput of 99,000,000 pounds/year. An example calculation for hourly particulate matter emissions from Fluid Bed 574 is given below:

$$\text{Eq. 4: } E_{\text{FB}} (\text{lb-PM/hr}) = [\text{Dry Feed (lb-material/hr)}] * [\text{Feed Loss Rate (0.0005\%)}] * [\text{Safety Factor (240\%)}] * [1 - \text{Collector Efficiency (95\%)}]$$

$$E_{\text{FB}} (\text{lb-PM/hr}) = [575 \text{ lb-material/hr}] * [0.0005] * [2.4] * [0.05]$$

$$E_{\text{FB}} (\text{lb-PM/hr}) = 0.035 \text{ lb-PM/hr}$$

Due to the very low emission rate, the permitted particulate matter emissions from the individual fluid beds are 0.10 lb/hr and 0.10 TPY.

### ***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 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 amounts of solvents used per batch, 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 emission rate of all the Coating Pans is 5.00 TPY and Mylan is not requesting any change in this limit.

Mylan has proposed the use of the RTO as a control for Coating Pans 244 and 245 for certain products. The hourly emission calculations for one Coating Pan are given below:

When exhausting straight to atmosphere, the following calculation applies:

**Eq. 5:** 
$$E_{CP} \text{ (lb-VOC/hr)} = [\text{Spray Gun Capacity (grams-solvent/hour)}] * [\text{VOC Content of Solvent (lb-VOC/gram)}]$$

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

$$E_{CP} \text{ (lb-VOC/hr)} = 396.9 \text{ lb-VOC/hr}$$

When exhaust from Coating Pans 244 and 245 are routed to the RTO (98% permitted control efficiency [9.1.5.]) for VOC control, the following calculation applies:

**Eq. 6:** 
$$E_{CP} \text{ (lb-VOC/hr)} = [\text{Spray Gun Capacity (grams-solvent/hour)}] * [\text{VOC Content of Solvent (lb-VOC/gram-solvent)}] * [1 - ((\text{RTO VOC Destruction Efficiency (\%)/100})]$$

$$E_{CP} \text{ (lb-VOC/hr)} = [180,000 \text{ grams-solvent/hour}] * [0.002205 \text{ lb-VOC/gram-solvent}] * [0.02]$$

$$E_{CP} \text{ (lb-VOC/hr)} = 7.94 \text{ lb-VOC/hour}$$

Mylan is not proposing any change to the particulate matter emissions from the Coating Pans.

## Oven Dryers

VOC emissions from the Oven Dryers 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 Oven Dryer 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.” Mylan has proposed an aggregate annual emission rate of all the Oven Dryers of 5.00 TPY (as of October 1, 2012).

Mylan has proposed the use of the RTO as a control for Oven Dryers 260-263 for certain products. Example hourly emission calculations for a single Oven Dryer are given below:

When exhausting straight to atmosphere, the following calculation applies:

**Eq. 7:** 
$$E_{OD} \text{ (lb-VOC/hr)} = [\text{Spray Gun Capacity (kg-solvent/hour)}] * [\text{VOC Content of Solvent (lb-VOC/kg-solvent)}]$$

$$E_{OD} \text{ (lb-VOC/hr)} = [240 \text{ kg/hour}] * [2.205 \text{ lb-VOC/kg-solvent}]$$

$$E_{OD} (\text{lb-VOC/hr}) = 529.20 \text{ lb-VOC/hour}$$

When exhaust from Oven Dryers 260-263 are routed to the RTO (98% permitted control efficiency [9.1.5.]) for VOC control, the following calculation applies:

**Eq. 8:** 
$$E_{OD} (\text{lb-VOC/hr}) = [\text{Uncontrolled VOC Emission Rate (lb-VOC/hour)}] * [1 - ((\text{RTO VOC Destruction Efficiency (\%)/100})]$$

$$E_{OD} (\text{lb-VOC/hr}) = [529.20 \text{ lb-VOC/hour}] * [0.02]$$

$$E_{OD} (\text{lb-VOC/hr}) = 10.59 \text{ lb-VOC/hour}$$

As the Oven Dryers are heated with steam from the already permitted boilers, there is no combustion exhaust associated with the units.

### **Regenerative Thermal Oxidation (RTO)**

Mylan is not proposing to increase the amount of solvent or fuel gas currently permitted to be combusted in the RTO (under R13-2068K, Mylan permitted maximum solvent and fuel gas combustion in the RTO even though they were not taking credit for controlling an equivalent amount of solvent at that time). Therefore, there is no collateral emissions increase associated with use of the RTO.

### **DAQ Review of Emission Calculation Methodologies**

The DAQ accepts the Mylan emissions calculations methodology as reasonable and practically enforceable using the requirements contained in the proposed draft permit.

### **Emissions Summary**

The quantifiable change in annual potential-to-emit (PTE) as a result of this permitting action will be -5.00 TPY of VOCs (as of September 1, 2011 from the reduction of annual fluid bed VOC emissions). The reduction in VOCs from the oven dryers is not calculable as a reasonable estimate of previous allowable emissions is not available. There is no increase in PTE of particulate matter from the increase in capacity of the fluid beds as the permitted emission limits were already in excess of the revised emissions reflecting the higher capacities.

### **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.

#### ***45CSR7: To Prevent and Control Particulate Air Pollution from Manufacturing Process Operations***

45CSR7 has two substantive requirements applicable to the Mylan manufacturing processes - defined as the production of various solid-dose pharmaceuticals. These are the opacity requirements

under Section 3 and the mass emission standards under Section 4. Each of these sections will be discussed below as they specifically relate to the fluid beds and coating pans.

45CSR7 Opacity Standards - Section 3

Section 3.1 sets an opacity limit of 20% on all applicable source operations. As the particulate matter emissions from the fluid beds and coating pans are controlled by inherent filters and cartridge collectors, opacity from these sources is expected to be minimal.

45CSR7 Weight Emission Standards - Section 4

Section 4.1 of 45CSR7 requires that each manufacturing processes meet a particulate matter stack emission limit based on the weight of material processed through the source operation (PWR). The emission limits are given under Table 45-7A and are based on the type source operation as defined in the Rule. The source operations subject to this Section are the cartridge collectors controlling the fluid beds and the coating pans. The following table, updated with the proposed new process weight rates, details the pertinent data for the compliance demonstration of each of these source operations.

**Table 2: 45CSR7 Section 4.1 Compliance<sup>(1)</sup>**

Source Operation	EP ID	Source Type	Unit PWR (lb/hr)	Aggregate PWR (lb/hr)	Table 45-7A Limit (lb/hr)	PTE (lb/hr)	Control Device
Fluid Bed	533	A	1,268	17,088	1.06	0.10	Cartridge Collector
Fluid Bed	534	A	551		0.46	0.10	Cartridge Collector
Fluid Bed	535	A	1,268		1.06	0.10	Cartridge Collector
Fluid Bed	536	A	551		0.46	0.10	Cartridge Collector
Fluid Bed	537	A	1,268		1.06	0.10	Cartridge Collector
Fluid Bed	538	A	551		0.46	0.10	Cartridge Collector
Fluid Bed	571	A	1,268		1.06	0.10	Cartridge Collector
Fluid Bed	572	A	551		0.46	0.10	Cartridge Collector
Fluid Bed	573	A	1,268		1.06	0.10	Cartridge Collector
Fluid Bed	574	A	551		0.46	0.10	Cartridge Collector
Fluid Bed	575	A	551		0.46	0.10	Cartridge Collector
Fluid Bed	576	A	1,268		1.06	0.10	Cartridge Collector
Fluid Bed	577	A	551		0.46	0.10	Cartridge Collector
Fluid Bed	578	A	1,268		1.06	0.10	Cartridge Collector
Fluid Bed	579	A	1,268		1.06	0.10	Cartridge Collector
Fluid Bed	580	A	1,268		1.06	0.10	Cartridge Collector
Fluid Bed	581	A	551		0.46	0.10	Cartridge Collector
Fluid Bed	582	A	1,268		1.06	0.10	Cartridge Collector

Source Operation	EP ID	Source Type	Unit PWR (lb/hr)	Aggregate PWR (lb/hr)	Table 45-7A Limit (lb/hr)	PTE (lb/hr)	Control Device
Coating Pan	215	A	750	3,245	0.84	0.84	Cartridge Collector
Coating Pan	241	A	750		0.84	0.84	Cartridge Collector
Coating Pan	242	A	245		0.28	0.28	Cartridge Collector
Coating Pan	244	A	750		0.84	0.84	Cartridge Collector
Coating Pan	245	A	750		0.84	0.84	Cartridge Collector

(1) These sources, for a conservative compliance demonstration, are considered “duplicate sources” as defined in 45CSR7. As such the PWR of all duplicate sources are aggregated and the resulting limit is distributed to each emission point relative to each source’s contribution to the total PWR.

***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***

While the potential change in emissions from the modification evaluated herein would have qualified the action for a Class II Administrative Update, due to the complexity of the changes required in the permit and the addition of new units to the permit (oven dryers), Mylan chose to submit the application as a modification.

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 June 17, 2011 in the *Dominion Post*. The affidavit of publication for this legal advertisement was submitted on July 12, 2011.

***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 issued a Title V permit on December 12, 2006. 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**

The modification evaluated herein will not result in any increase of non-criteria regulated pollutants.

**AIR QUALITY IMPACT ANALYSIS**

The proposed modification does not meet the definition of a “major modification” pursuant to 45CSR14 and, therefore, an air quality impact (computer modeling) analysis was not required.

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

The monitoring, compliance demonstration, record-keeping, and reporting (MCRR) used to allow Mylan to take credit for control of two Fluid Beds with the Absorber, two Coating Pans with the RTO, and four Oven Dryers with the RTO are based on the MCRR used previously to allow Mylan to take credit for controlling emissions of VOCs from the Fluid Bed with the RTO (as permitted under R13-2068N). This methodology sets up an actual emissions monitoring system to show compliance on a rolling monthly basis with annual VOC emission limits. Within this monitoring system, control device performance is also monitored and parameters must be maintained within certain ranges. The permit requires record-keeping of all excursions of these ranges and a prohibition of using the minimum VOC destruction efficiency of the RTO or Absorber in actual emissions reporting during times of these measured excursions. The monitored parameter on the Absorber is the liquor flow rate.

## TESTING OF OPERATIONS

The permit requires, with respect to the use of the Absorber for control of VOCs from the Fluid Beds, the following testing requirement [11.3.1.]:

- Within 60 days after achieving the maximum solvent exhaust rate at which the absorber is permitted to operate at, but not later than 180 days after the initial use of the absorber to control of VOCs during a Fluid Bed production run, and at such times thereafter as may be required by the Secretary, the permittee shall conduct, or have conducted, a performance test on the absorber to determine compliance with the minimum VOC destruction efficiency as given under 11.1.4. The permittee shall use EPA approved test methods unless granted approval in writing by the Director to use an alternative test method in a protocol submitted pursuant to 3.3.1.c.

## CHANGES TO PERMIT R13-2068N

The substantive changes made to Permit R13-2068N are:

- Updated all relevant information under Table 1.0 of the permit;
- Updated particulate matter limits for boilers to include PM<sub>2.5</sub> and condensables [5.1.5., 5.1.6., 5.1.7., 5.1.8.];
- Corrected Fluid Bed 45CSR7 PM limits [6.1.2.];
- Added parenthetically that Fluid Bed particulate matter emission limits include PM<sub>2.5</sub> and PM<sub>10</sub>. [6.1.3.];

- Addition of language requiring RTO control capability of appropriate fluid beds [6.1.6];
- Added new VOC hourly limit for Fluid Beds exhausting to Absorber [6.1.4(c)];
- Added reduced annual aggregate VOC limit for all Fluid Beds [6.1.5(b)];
- Increased Fluid Bed per-load material loading limits [6.1.6(a)(1) and (2)];
- Added language for Fluid Bed exhaust to Absorber or directly to atmosphere [6.1.6(f)];
- Added and revised language under the Fluid Bed VOC compliance demonstration requirements so as to authorize taking credit for reductions from the Absorber [6.2.5.];
- Corrected Coating Pan 45CSR7 PM limits [8.1.2.];
- Added language so that Coating Pan particulate matter emission limits include PM<sub>2.5</sub> and PM<sub>10</sub>. [8.1.3];
- Added new VOC hourly limit for Coating Pans exhausting to RTO [8.1.4(b)];
- Added language for Coating Pan exhaust to RTO or directly to atmosphere [8.1.6(f)];
- Added requirements for Coating Pan VOC compliance demonstration so as to authorize taking credit for reductions from the RTO [8.2.5.];
- Added new Coating Pans and Oven Dryers to the RTO requirements [9.1.5, 9.1.7, & 9.2.3];
- Added requirements for the Oven Dryers [10]; and
- Added requirements for the Absorber [11].

RECOMMENDATION TO DIRECTOR

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

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Joe Kessler, PE  
Engineer

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Date

Fact Sheet R13-2068O  
Mylan Pharmaceuticals Inc.  
Chestnut Ridge