

**NORTH CAROLINA DIVISION OF
AIR QUALITY**

Air Permit Review

Permit Issue Date: PROPOSED

Region: Raleigh Regional Office
County: Durham
NC Facility ID: 3200289
Inspector's Name: Brian Bland
Date of Last Inspection: 04/23/2008
Compliance Code: 3 / In Compliance - Inspection

Facility Data			Permit Applicability (this application only)	
Applicant (Facility's Name): Eisai Inc Facility Address: Eisai Inc 900 Davis Drive Site 13 Research Triangle Park, NC 27709 SIC: 2834 / Pharmaceutical Preparations NAICS: 325412 / Pharmaceutical Preparation Manufacturing Facility Classification: Before: Title V After: Title V Fee Classification: Before: Title V After: Title V			SIP: NSPS: NESHAP: PSD: PSD Avoidance: Revised NC Toxics: 112(r): Other:	
Contact Data			Application Data	
Facility Contact	Authorized Contact	Technical Contact	Application Number: 3200289.09A Date Received: 02/02/2009 Application Type: Renewal Application Schedule: TV-Renewal Existing Permit Data Existing Permit Number: 08374/T09 Existing Permit Issue Date: 11/17/2008 Existing Permit Expiration Date: 10/31/2009	
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Review Engineer: Jenny Kelvington Review Engineer's Signature: _____ Date: _____		Comments / Recommendations: Issue 08374/T10 Permit Issue Date: Permit Expiration Date:		

I. Purpose of Application

This permitting action is a renewal of an existing Title V permit pursuant to 2Q .0513. The existing Title V permit (**08374T09**) was issued on November 17, 2008 and is scheduled to expire on October 31, 2009. The renewal application was received on February 2, 2009, at least nine months prior to the expiration date. Therefore, the existing permit shall not expire until the renewal permit has been issued or denied. All terms and conditions of the existing permit shall remain in effect until the renewal permit has been issued or denied.

II. Facility Description

Eiasi is a pharmaceutical facility located in Research Triangle Park, Durham County, North Carolina, which produces two products, Aciphex and Aricept, for the treatment of acid reflux and Alzheimer's, respectively. These products may be either prepared in granular form and dried in a steam heated fluidized bed dryer or pressed into tablets and then coated. The Aciphex preparations require the use of ethanol as the solvent. Water is the solvent for Aricept preparations.

III. Permit History

November 20, 1996 – The initial air quality permit (08374R00) was issued.

July 5, 2000 - The initial Title V Permit 08374T03 was issued with an expiration date of June 30, 2005.

November 19, 2004 – Permit 08374T07 was issued for the renewal of the TV permit extending the expiration date to October 31, 2009.

April 4, 2007 - Permit 08374T08 was modified to add a NSPS natural gas-fired boiler (ID No. ES-10) at the facility's Central Utilities Building.

June 10, 2008 – Start-up date for Boiler ES10.

November 17, 2008 - Permit 0837408 was modified to add two NSPS diesel-fired emergency generators (ID Nos. ES11 and ES12). Start-up is planned for 2010.

IV. Facility Compliance Status

The DAQ has reviewed the compliance status of this facility. Brian Bland (RRO) last inspected the facility on April 23, 2008 and found the facility appeared to be in compliance with all applicable requirements. No notices of violations have been issued to the facility in the last five years. The applicant has certified that the facility will be in compliance with all applicable requirements at the time of permit issuance and will continue to comply with these requirements. The applicant has also certified that the facility will be in compliance with any applicable requirements taking effect during the term of the permit and will meet such requirements on a timely basis.

V. Permit Changes

The following table lists all modifications associated with this permit action:

Page(s)	Current Section	Description of Change(s)
Cover	-	-amended all dates and permit revision numbers
All	Header	-amended permit revision number
3	1 (table)	-removed footnotes for ES-10, 11, & 12. The permit shield and compliance certification now applies to all permitted sources.
10	2.1.E (table)	-remove PSD avoidance condition limiting NO _x emissions
12	2.1.E.4.	-remove PSD avoidance condition limiting NO _x emissions
13	2.2.A	-change VOC emission limit for the tablet coaters and fluidized bed dryers combined from < 248.36 to <247 tons per year to ensure facility wide VOC emissions remain below 250 tons per year for PSD avoidance.
15-24	Section 3 General Conditions	-updated shell language

VI. Permitted Sources

Tablet Coaters (ID Nos. ES-1, ES-6 and ES-7) with HEPA filters (ID Nos. CD-1, CD-3 and CD-4)
The tablet coaters apply an external coating and undercoating to powdered tablets. The coatings, either ethanol or water based, are sprayed onto tablets in a rotating pan. Emissions are vented to a high efficiency particulate attenuation (HEPA) filter.

Steam Heated Fluidized Bed Dryers (ID No. ES-2, ES-8 and ES-9) with HEPA filters (ID No. CD-2, CD-5 and CD-6)
The fluidized bed dryers are designed to remove the ethanol or water-based solvent from granular preparations. Emissions are vented to a high efficiency particulate attenuation (HEPA) filter.

Three Natural Gas-Fired Boilers (ID Nos. ES-3, ES-4 and ES-10) **NSPS**
The boilers fire natural gas and were manufactured after June 9, 1989. Boilers ES-3 and ES-4 each have a heat input rating of 20.925 (21) million Btu per hour and previously operated in a lead-lag configuration. During the April 2008 facility inspection, the lead boiler was operating at 125 psi with no visible emissions observed from the common stack. On June 10, 2008, Eiasi placed the third boiler, ES-10, 26.8 million Btu per hour heat input, in service. Although it is physically possible to operate all three boilers at one time, only the two smaller boilers (ES-3 and ES-4) together or the one larger boiler (ES-10) by itself operate at any given time.

No. 2 Fuel Oil-Fired Emergency/Peak Shaving Generator (ID No. ES5)
The generator is a Spectrum Detroit Diesel 750 generator rated at 750 kW (1,006 HP) and consumes up to 63.12 gallons per hour of No. 2 fuel oil. During the April 2008 facility inspection, the generator was not operating. However, DAQ has previously observed the generator start up and operate with the exhaust always quickly clearing to at or near 0% opacity.

No. 2. Fuel-Oil Fired Emergency Generators (ID Nos. ES11 and ES12) **NSPS**
These generators were added to the permit with the last modification in November 2008 and have not yet been placed into operation. According to Mr. Greg Baker, the generators installation is planned for 2010. Each generator will have a maximum engine power not to exceed 3,000 kW (electric) [4,021 HP (electric)] and are currently limited to 300 annual operating hours under a PSD avoidance condition. With the renewal, the PSD avoidance condition will be removed and emergency use of the generators will not be limited.

VII. Regulatory Review

The facility is currently subject to the following regulations:

- 15A NCAC 2D .0503, Particulate Matter Emissions from Boilers
- 15A NCAC 2D .0515, Particulates from Miscellaneous Industrial Processes
- 15A NCAC 2D .0516, Sulfur Dioxide Emissions from Combustion Sources
- 15A NCAC 2D .0521, Control of Visible Emissions
- 15A NCAC 2D .0524, New Source Performance Standards, Subpart Dc for Boilers
- 15A NCAC 2D .0524, New Source Performance Standards, Subpart IIII for CI ICEs
- 15A NCAC 2D .0958, Work Practices for Sources of Volatile Organic Compounds
- 15A NCAC 2D .1806, Control and Prohibition of Odorous Emissions
- 15A NCAC 2D .1111, MACT [40 CFR 63 SUBPART ZZZZ]
- 15A NCAC 2Q .0307, Avoidance of 15A NCAC 2D .0530

2D .0503: Particulate matter emissions from boilers (ID Nos. ES-3 and ES-4) shall not exceed **0.41 lb/million BTU** and (ID No. ES-10) shall not exceed **0.36 lb/million BTU**. Maximum particulate emissions from the firing of natural gas in these boilers are expected to be **0.01 lb/million Btu**. Compliance is indicated. No monitoring, record keeping or reporting is required.

2D .0515: Particulate matter emissions from coaters and dryers (ID Nos. ES-1, ES-2, ES-6, ES-7, ES-8 and ES-9) shall not exceed the following allowable emission rates:

Source	Process Rate (ton/hr)	Allowable PM Emissions (lb/hr)	Uncontrolled Particulate Emission Rate (lb/hr)	Controlled Particulate Emission Rate (lb/hr)
ES-1, tablet coater	0.060	0.622	0.3	0.00009
ES-6, tablet coater ¹	0.060	0.622	0.3	0.00009
ES-7, tablet coater ²	0.072	0.702	1.0	0.0003
ES-2, fluidized bed dryer	0.30	1.84	2.35	0.0007
ES-8, ES-9 (each), fluidized bed dryer ²	0.070	0.693	0.5	0.00015

1. The rate information for ES-1 was used since both tablet coaters are identical.
2. Tablet coater ES-7 and dryers ES-8 and ES-9 were permitted with the T04 modification. The permit only required the dryers to be controlled by HEPA filters. The pre-controlled emission data for these sources may have been reversed since more emissions are expected from the fluidized bed dryers.

The above process and emission rate information was obtained from previous permit reviews. All sources are in compliance with the 2D .0515 particulate limits. Based on the uncontrolled emissions data, the fluidized bed dryers (ID Nos. ES-8 and ES-9) and tablet coaters (ID Nos. ES-1 and ES-6) do not require the use of the HEPA filters to achieve compliance, whereas particulate control is necessary for tablet coater (ID No. ES-1) and fluidized bed dryer (ID No. ES-2). However, more particulates are expected from the fluidized bed dryers as they process granular powders, which tend to produce more emissions than the tablet coating. DAQ expects tablet coater (ES-7) generates less 0.7 lbs/hr of pre-control particulates while dryers ES-8 and ES-9 give off more than 0.7 lbs/hr of pre-control particulates. Therefore, the current permit condition requiring particulate emissions from all of the fluidized dryers to be controlled with HEPA filters and routinely inspected will remain. Additionally, no monitoring/recordkeeping/reporting will be added for any of the tablet coaters. The facility has consistently performed the routine inspections of the ductwork and structural integrity of the HEPA filters associated with the dryers. Continued compliance is expected.

2D .0516: Sulfur dioxide emissions from combustion sources (ID Nos. ES-3, ES-4, ES-5 ES-10, ES-11, and ES-12) shall not exceed 2.3 pounds per million Btu heat input. All combustion sources fire either natural gas or distillate oil. The highest SO₂ emission rate will be 0.505 pounds per million Btu heat input when the facility fires No. 2 containing up to 0.5% sulfur in the generators. Thus, compliance is indicated. No monitoring, record keeping or reporting is required.

2D .0521 Visible emissions from all sources (ID Nos. ES-1 through ES-12) shall not be more than 20 percent opacity. The facility appears to be in compliance. In the past five inspection reports, Mr. Brian Bland stated that no VEs were observed during the inspection. No monitoring, record keeping or reporting is required.

2D .0524 NSPS requirements [Subpart Dc] for the boilers (ID Nos. ES-3, ES-4 and ES-10)

The current permit requires Eiasi to record monthly the amount of fuel combusted, maintain records for two years, and submit summary reports twice a year. According to the inspection reports, Eiasi maintains daily fuel usage records and has satisfied all reporting provisions. Compliance is indicated.

2D .0524 NSPS requirements [Subpart IIII] for the generators (ID Nos. ES-11, and ES-12)

Under NSPS, Subpart IIII the new emergency generators, permitted in November 2008, must

(1) not exceed the following emissions standards:

HC: 1.3 g/kW-hr (1.0 g/HP-hr),

NOx: 9.2 g/kW-hr (6.9 g/HP-hr),

CO: 11.4 g/kW-hr (8.5 g/HP-hr), and

PM: 0.54 g/kW-hr (0.4 g/HP-hr);

(2) burn diesel fuel with sulfur content of less than 500 ppm beginning October 1, 2007 and with sulfur content of less than 15 ppm beginning October 1, 2010;

(3) be equipped with a non-resettable hour meters prior to startup;

(4) if equipped with diesel particulate filters to comply with the emission limits, have backpressure monitors on each diesel filter to indicate when the high backpressure limit of the engine is approached;

(5) be operated in accordance with the manufacturer's written instructions or procedures developed by the Permittee that are approved by the manufacturer;

(6) be model year 2007 or later CI ICE certified to the emission standards in §60.4205(b); and

(7) limit operation to actual emergencies, maintenance checks, and readiness testing.

The existing permit requires Eiasi to submit semi-annual reports of monitoring and record-keeping activity. These conditions will remain in the permit. Compliance is expected.

2D .0958: Work Practice Standards for VOC Sources (ID Nos. ES-1, ES-2, and ES-6).

To assure compliance, the Permittee shall, at a minimum, perform a visual inspection once per month of all operations and processes utilizing volatile organic compounds during normal operations, record the inspection results in a logbook, and immediately initiate any required corrective action. The Permittee shall submit a summary report of the observations semi-annually. The facility has appeared to be following all work practice standards during the last five annual inspections. Continued compliance is expected.

2D .1806: Control and Prohibition of Odorous Emissions

The DAQ Raleigh Regional Office has not detected any objectionable odors during the annual facility inspections or received any odor complaints concerning Eiasi. Continued compliance is expected.

2D .1111, MACT Subpart ZZZZ "National Emission Standards for Hazardous Air Pollutants for Reciprocating Internal Combustion Engines (RICE MACT)"

The RICE MACT applies to reciprocating internal combustion engines (RICE) located at a major HAP source as well as RICE, whose construction commenced on or after June 12, 2006, at a area source location. Eiasi is not a major source of HAP emissions but will commence construction of the RICE after 2006. Therefore, the RICE MACT applies. Since the generators are subject to NSPS, Subpart IIII, MACT only requires the RICE to meet all the applicable NSPS requirements. Compliance is expected.

2Q .0307: Limitation To Avoid PSD; 2D .0530 -

A chemical process plant is a listed source category with a 100 tpy major source threshold only if the process involves a chemical reaction. If no chemical reaction occurs, the source is not a listed source and therefore the major source threshold is 250 tpy. In the initial TV review (App. No.

3200289.00B), Mr. Michael Brandon, DAQ Permit Engineer, noted the 250 TPY threshold applied to Eiasi because the no chemical reaction occurs within the product manufacturing. Eiasi's maximum unrestricted VOC emissions are greater 250 tons per year and therefore the facility took enforceable permits restrictions to avoid PSD review.

Since the initial permit in 1996, Eiasi has always desired to stay a minor source and has requested a PSD avoidance condition to ensure facility wide VOC emissions are limited to less than 250 tons per consecutive 12-month period. Emission inventory data and semi-annual reports to the RRO indicate they have consistently remained below the PSD threshold. The emission inventory from 2003 to 2007 shows the highest annual facility-wide VOCs emissions at 219.16 tons, which occurred in 2005. Furthermore, the highest 12-month rolling average reported in the inspection reports, occurred in the second half of 2005 report at 226.6 tons VOCs emitted from December 2004 to November 2005. The inspection reports also note that the facility has submitted VOC summary reports to the RRO in a timely and complete manner and maintains a good on-site logbook documenting the monthly VOC emissions.

When the permit was modified in November 2008 to add the two emergency generators, the permit engineer was not aware that Eiasi desired to remain a minor source and extend the PSD avoidance condition to include the generators. The review states:

“Eiasi’s RTP facility is “250 tons” industrial category source. The facility wide total potential emissions of all existing sources are approximately 250.2 tons annually. Hence, the facility is deemed an existing major source for PSD and any “significant” modification to this existing major source must be reviewed for PSD.

As can be seen in the above emission summary, the potential NOx emissions (based on 500 hours of operation) from two generators are approximately 61 tons/yr. Because the potential NOx emissions from the sources exceed its significant threshold of 40 tons per year, major modification review is triggered for PSD. The Permittee has requested to obtain a federally enforceable permit condition to limit NOx emissions to less than 40 tons/yr to avoid triggering PSD review by restricting hours of operations for each generator to 300 hrs per consecutive 12-month period. At this restricted operation, the total NOx emissions from the proposed generators will be approximately 36.3 tons/yr, which are less than 40 tons/yr. The permit condition limiting NOx emissions to less than 40 tons on a consecutive 12-month basis will be included in the revised permit. Necessary monitoring / recordkeeping / reporting will be included to assure compliance with the limit.”

When the permit was revised in 2007 to add the third boiler, the potential 0.18 tpy of VOCs emitted from generator ES-5 was not considered significant enough to warrant revising the facility-wide cap of 250 tpy.

The PSD condition in the existing permit will be updated to recognize that the generator ES-5 and boiler ES-10 contribute VOC emissions to the facility total potentials. On March 4, 2009, Mr. Greg Baker requested that combined VOC emissions from the tablet coaters and fluidized bed dryers (ID Nos. ES-1, ES-2, ES-6, ES-7, ES-8 and ES-9) be limited to less than 247 tons per year. The table below includes emission unit level PTE's for VOCs.

Emission Source	Unrestricted Potential VOC Emissions (tons per year)	Maximum VOC Emissions with Avoidance Condition (tons per year)
Tablet coaters ES-1, 6, & 7	552.9	< 247
Dryers ES-2, 8, & 9	96.3	
Boiler ES-3	0.51	3
Boiler ES-4	0.51	
Generator ES-5	0.18	
Boiler ES-10	0.64	
Generator ES-11	0.59	
Generator ES-11	0.59	
Facility Wide Total*	652.22	< 250

* Any VOC emissions, which could possibly occur from the coating solution preparation dust collection system (IS-3), are included in the emissions from the tablet coaters. VOC emissions from the ethanol storage tank (IS-4) are negligible since the tank is equipped with a nitrogen blanket. No other insignificant activity emits VOCs.

The significant threshold of 40 tpy of NOx for new emergency generators will be removed from the permit, as it is no longer applicable. Potential facility wide NOx emissions are 97.78 tpy and below the 250 tpy major source classification.

VIII. NSPS, NESHAPS/MACT, PSD, 112(r), CAM, Facility Wide Toxics

NSPS – The facility is currently subject to New Source Performance Standards (NSPS). Subpart Dc applies to the three boilers and Subpart IIII applies to the last two generators.

NESHAPS/MACT - Based on a review of the facility’s current operations and emissions sources, the facility is not subject to the MACT for pharmaceutical production (40 CFR 63, Subpart GGG) since no HAPs are used in the manufacturing operations. HAP emissions only occur from combustion sources, which have a total HAP potential of less than 1 ton per year. The new generators are subject to MACT ZZZZ as an area source. See Section VII for a discussion.

PSD – The facility is a minor source located in Durham County, which is in attainment or non-classified for all criteria pollutants. See Section VII regarding minor source status.

112(r) – The facility is not subject to Section 112(r) of the Clean Air Act requirements because it does not store any of the regulated substances in quantities above the thresholds in the Rule. The permit renewal does not affect this status.

CAM – Compliance Assurance Monitoring (CAM) (40 CFR Part 64) does not apply because no source at the facility would be major if uncontrolled. The maximum pre-controlled particulate emission rate of any source with emissions control equipment is 4.4 tons per year.

Facility Wide Air Toxics – The facility is not currently subject to any facility-wide air toxics limitations. The only toxic pollutants emitted from the facility are from fuel combustion sources.

IX. Facility Emissions Review

The following is an emission summary for this facility. Actual emissions are for year 2007 as reported by the company to DAQ through submittal of annual emission inventories. Potential emissions, with the exception of HAPs, are copied from the most recent permit application for Permit No. 08374T09.

Pollutant	Actual Emissions Tons/Yr	Potential Emissions Tons/Yr
PM	0.37	2.87
PM10	0.37	2.87
PM2.5	0.37	2.87
CO	4.06	34.70
NOx	5.09	97.78
SO ₂	0.14	2.41
VOC	180.5	< 250
Single largest HAP [n-Hexane]	0.085	< 1
Total HAPs	0.085	< 1

X. Review of Permit Changes Recommended by Facility and Region

The RRO was provided a draft permit to review on February 28, 2009. Mr. Charles McEachern, RRO, recommends issuance of the renewed air permit.

Mr. Greg Baker, Eisai Safety and Environmental Manager, was provided a draft permit to review on March 2, 2009. Mr. Baker had no comments.

XI. Public Notice/EPA and Affected State(s) Review

Pursuant to 15A NCAC 2Q .0521, a notice of the DRAFT Title V Permit shall be placed in a newspaper of general circulation in the area where the facility is located. The notice will provide for a 30-day comment period, with an opportunity for a public hearing. Copies of the public notice shall be sent to persons on the Title V mailing list and EPA. Pursuant to 15A NCAC 2Q .0522, a copy of each permit application, each proposed permit and each final permit pursuant shall be provided to EPA. Also pursuant to 2Q .0522, a notice of the DRAFT Title V Permit shall be provided to each affected State at or before the time notice provided to the public under 2Q .0521 above.

XI. Conclusions, Comments, and Recommendations

A professional engineer's seal was not required for this renewal.
A consistency determination was not required for his renewal.