

AIR PERMIT REVIEW

APPLICANT: Eisai, Inc.	SITE LOCATION: Research Triangle Park	COUNTY: Durham
TECHNICAL CONTACT: Greg Baker	PHONE: (919) 474-2183	RESPONSIBLE OFFICIAL: Larry Kranking
REVIEW ENGINEER: Mark Cuilla	SIGNATURE:	TITLE: Vice President
REGIONAL CONTACT: Charles McEachern	REGIONAL OFFICE: RRO	SIC CODE: 2834
APPLICATION NUMBER: 3200289.04A	EXISTING PERMIT NUMBER: 08374T06	NEW PERMIT NUMBER: 08374T07

I. Purpose of Application

The facility currently operates under a title V permit that will expire on June 30, 2005. This application addresses the requirement that the facility submit a renewal application by September 30, 2004. In addition, the facility is requesting that two insignificant activities under 15A NCAC 2Q .0503(8) be deleted because:

- tablet press duct collection system (**ID No. IS-2**) does not discharge to the outside environment (its HEPA filter discharges inside the facility); and
- coating solution preparation dust collection system (**ID No. IS-4**) does not have a collection/controlled system, only room air is discharged.

The Permittee indicates that there have been no modifications made or new equipment added since the issuance of Permit No. 08374T06 on December 29, 2002.

II. Facility Description

Eisai Inc., is a pharmaceutical manufacturer. Currently the facility is producing two products, Aricept and Aciphex, for the treatment of Alzheimer’s and acid reflux, respectively.

III. History/Background/Application Chronology

November 14, 2002 – Permit 08374T05 issued as a 502(b)(10) modification for the construction and operation of one tablet coater (ID No. ES-7) and two steam heated fluidized bed dryers (ID Nos. ES-8 and ES-9).

December 18, 2002 – Permit 08374T06 issued to make administrative corrections.

June 28, 2004 – Permit renewal application was received by Raleigh Regional Office and sent to Central Office for processing.

July 20, 2004 – Letter sent to facility indicating that the permit application was technically incomplete because it did not contain a discussion of CAM.

July 26, 2004 – Received response to incompleteness determination. Permit application now deemed complete for processing.

IV. Permit Modification/Changes

The following table describes the modifications to the current permit as part of the renewal process.

Page(s)	Section	Description of Change(s)
Attachment	Insignificant Activities	-added ID Nos. -amended permit revision number
Cover	-	-amended all permit revision numbers and dates
TOC	TOC	-removed reference to Part II -added reference to Part I, Section 2.3
All	Header	-amended permit revision number
3	Equipment list	-added Subpart Dc references to ES-3 and ES-4 -removed asterisk for 502(b)(10) modification and associated foot note
4	2.1 A.1.a-c	-updated language to most recent shell conditions (tvcond54.doc) -added equipment ID Nos. where needed
5	2.1 A.2.a-c	-updated language to most recent shell conditions (tvcond54.doc) -added equipment ID Nos. where needed
5-6	2.1 B.1.a-f	-updated language to most recent shell conditions (tvcond54.doc) -added equipment ID Nos. where needed
6	2.1 B.2.a-c	-updated language to most recent shell conditions (tvcond54.doc) -added equipment ID Nos. where needed -removed monitoring/recordkeeping/reporting requirement per RRO request
7	2.1 C.1.a-c 2.1 C.2.a-c 2.1 C.3.a-c	-updated language to most recent shell conditions (tvcond54.doc) -added equipment ID Nos. where needed
8	2.1 C.4.a-c	-updated language to most recent shell conditions (tvcond54.doc) -added equipment ID Nos. where needed
8	2.1 D.1.a-c	-updated language to most recent shell conditions (tvcond54.doc) -added equipment ID Nos. where needed
8-9	2.1 D.2.a-c	-updated language to most recent shell conditions (tvcond54.doc) -added equipment ID Nos. where needed
9	2.2 A.1.a-d	-updated language to most recent shell conditions (tvcond54.doc) -added equipment ID Nos. where needed
10	2.3 A.1	-moved permit condition from Section 2.2 to 2.3 -updated language to most recent shell conditions (tvcond54.doc) -added equipment ID Nos. where needed
11-19	General Conditions	-updated to most recent shell conditions (v2.5)

V. Regulatory Review

The facility is subject to the following regulations:

15A NCAC 2D .0503, Particulates from Fuel Burning Indirect Heat Exchangers
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, NSPS 40 CFR Part 60 Subpart Dc
15A NCAC 2D .0958, Work Practice Standards
15A NCAC 2D .1806, Control and Prohibition of Odorous Emissions
15A NCAC 2Q .0317, Avoidance Conditions (for 15A NCAC 2D .0530, Prevention of Significant Deterioration)

Permit modification history and review: On November 14, 2002, the facility was issued a permit modification for the installation of one tablet coater (**ID No. ES-7**) and two steam heated fluidized bed dryers (**ID Nos. ES-8 and ES-9**). This modification was processed as a 502(b)(10) modification; therefore, public notice and EPA review was not completed. As part of this renewal process the equipment will be processed with proper notice and review periods.

The proposed equipment is subject to the particulate standards of 15A NCAC 2D .0515. Per 2D .0515, allowable emissions are calculated using the following formula:

$$E = 4.10 \times P^{0.67},$$

where P is the process rate in tons per hour and E is the allowable emission rate in pounds per hour. Per the permit application and as noted in Mike Benson's review (**3200289.02C**) for **ES-7**, the process rate is 0.0717 tons per hour. This equated to an allowable emission rate of 0.702 pounds per hour. After control emissions were estimated as 0.0003 pounds per hour indicating compliance. For the emission sources **ES-8** and **ES-9**, the process rate is 0.0704 tons per hour. This equated to an allowable emission rate of 0.693 pounds per hour. After control emissions were estimated as 0.00015 pounds per hour indicating compliance. The tablet coater is not subject to any monitoring, recordkeeping, or reporting requirements. To ensure compliance with the particulate standard, monthly visual inspections and annual structural inspections of the HEPA filters installed on the fluidized bed dryers are required. The Permittee is required to record all monitoring activities in a logbook indicating the date and time of all inspections, the results of the inspections, the results of any maintenance performed, and any variances from manufacturer's recommendations. A summary of these records is required to be reported semi-annually. At the most recent inspection of the facility, RRO did not indicate any compliance issues; therefore, continued compliance is expected.

The proposed equipment is subject to the 20 percent opacity standard of 15A NCAC 2D .0521. This condition states that visible emissions from the proposed equipment shall not be more than 20 percent opacity when averaged over a six-minute period. However, six-minute averaging periods may exceed 20 percent not more than once in any hour and not more than four times in any 24-hour period. In no event shall the six-minute average period exceed 87 percent. Mike Benson indicated in his permit review that previous inspections have shown similar equipment to be in operation at full capacity with no noted visible emissions present. It was expected that the proposed equipment would operate in a similar manner with no noted visible emissions present; therefore, continued compliance is expected. The Permittee is not required to complete monitoring, recordkeeping, or reporting activities for the tablet coatiers. Per the latest inspection of the facility, RRO recommends that the monitoring, recordkeeping, and reporting requirements for visible emissions from the fluidized bed dryers be removed from the permit. This renewed permit has made this change.

VI. NSPS, NESHAPS, PSD, Attainment Status, 112(r), CAM

NSPS

The facility's two natural gas-fired boilers (**ID Nos. ES-3 and ES-4**) are subject to the recordkeeping requirement for monthly fuel usage [40 CFR 60, Subpart Dc]. This renewal request does not change this requirement; therefore no permit modifications are necessary.

NESHAP/MACT

The facility is not a major source of HAP emissions; therefore it is not subject to any applicable MACTs. This renewal request does not change this requirement; therefore no permit modifications are necessary.

PSD

The facility currently operates under a PSD avoidance condition for VOCs from the three tablet coaters and three steam heated fluidized bed dryers. This equipment is limited to less than 250 tons VOC per consecutive 12-month period. The Permittee is required to calculate VOC emissions per month and record these calculations in a logbook. This renewal request does not change this requirement; therefore no permit modifications are necessary.

112(r)

This 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. This renewal request does not change this requirement; therefore no permit modifications are necessary.

CAM

CAM is applicable to a facility if:

1. the unit is subject to an emission limitation or standard;
2. the unit uses a control device to achieve compliance; and
3. the unit has potential pre-control device emissions of the applicable regulated air pollutant that are equal to or greater than 100 percent of the amount, in tons per year, required for a source to be classified as a major source.

The facility has six permitted control devices to only control dust emissions from the three tablet coaters and three steam heated fluidized bed dryers. Based only on particulate emissions, the tablet coaters and fluidized bed dryers would be insignificant activities because emissions are less than 5 tons per year (15A NCAC 2Q .0503(8)). Therefore, CAM does not apply for the control of particulate emissions.

However, the tablet coaters and fluidized bed dryers are not insignificant because of VOC emissions. The permitted control equipment is not in place for the control of VOCs, therefore CAM does not apply.

VII. Facility Wide Air Toxics

The facility is not currently subject to air toxics permit conditions. This renewal request does not change this requirement; therefore no permit modifications are necessary.

VIII. Statement of Compliance

The facility was last inspected on April 30, 2004, by Brian Bland of the Raleigh Regional Office. No compliance problems were discovered at the facility during the inspection and the facility appeared to be in compliance with all permitting requirements.

IX. Facility Emissions Review

There is no change in emissions for this renewal. The following table represents facility wide emissions as submitted by the facility in its latest emissions inventory:

Pollutant	2002 Emissions (tons per year)
CO	2.94
NOx	3.78
PM10	0.2
SO ₂	0.12
VOC	134.28
Total HAPs	127.69 (pounds per year)

X. Stipulation Review

Per an August 9, 2004 review of the DRAFT permit, the RRO had the following comments, *“the most recent inspector has requested that the bi-annual VE monitoring of the fluidized bed dryers be removed and replaced with no monitoring requirement (condition 2.2 B.2.c). Also, he reports that there are some 10,000 gallon ethanol storage tanks that are a source of title V pollutants (VOCs) and should be on the insignificant activities list.”* These changes have been made in the final DRAFT permit.

XI. Conclusions, Comments, and Recommendations

The Permittee requested as part of this renewal that two insignificant activities be removed as follows:

- tablet press duct collection system (**ID No. IS-2**) does not discharge to the outside environment (its HEPA filter discharges inside the facility); and
- coating solution preparation dust collection system (**ID No. IS-4**) does not have a collection/controlled system, only room air is discharged.

While it is true that these pieces of equipment only discharge their particulate emissions through filters into the facility itself, they are also fugitive sources of VOC emissions. The facility currently operates under a PSD avoidance condition for VOC emissions. Therefore, this equipment must remain on the permit as insignificant sources.

RCO recommends issuance of the renewed permit upon completion of the required 30 day public notice period and 45 day EPA review period.

This renewal request did not require the submittal of a consistency determination or professional engineer’s seal.