ILLINOIS ENVIRONMENTAL PROTECTION AGENCY

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DOUGLAS P. SCOTT, DIRECTOR

217/782-5544
217/782-9143 (TDD)

May 12, 2010

CERTIFIED MAIL
RETURN RECEIPT REQUESTED
7008 1830 0001 4720 7998

Cheryl Newton, Director
Air and Radiation Division
United States Environmental
Protection Agency Region V
77 West Jackson Boulevard, AR-18J
Chicago, Illinois 60604-3598

Attn: Steven Rosenthal:

Re: **R08-8: IN THE MATTER OF: ABBOTT LABORATORIES' PROPOSED SITE-SPECIFIC AMENDMENT TO APPLICABILITY SECTION OF ORGANIC MATERIAL EMISSION STANDARDS AND LIMITATIONS FOR THE CHICAGO AREA; SUBPART T: PHARMACEUTICAL MANUFACTURING (35 ILL. ADM. CODE 218.480(b))**

Dear Ms. Newton:

Pursuant to Section 110(a)(2) of the Clean Air Act (CAA) (42 U.S.C. §7410 (a)(2)), and Section 28 of the Illinois Environmental Protection Act (415 ILCS 5/28), the Illinois Environmental Protection Agency ("Illinois EPA") submits the following amendments to the Illinois State Implementation Plan (SIP). Abbott Laboratories' ("Abbott") filed a petition with the Illinois Pollution Control Board ("Board") to amend Subpart T: Pharmaceutical Manufacturing (35 Ill. Adm. Code 218.480(b)). Abbott proposed a source-specific cap on emissions of volatile organic material ("VOM") from its combined fluid bed dryers and tunnel dyers in lieu of rate-based limits provided in Section 218.480(b). The net effect of the proposal will result in a reduction of 24.5 tons per year of VOM emissions. This letter relates to the formula to be used by Abbott determining annual compliance.

It is the Illinois EPA's interpretation that compliance with the annual VOM emissions limit in Section 218.480(4) of 35 Ill. Adm. Code concerning Abbotts 20.6 tons VOM per year limit, shall be determined on a monthly basis from the sum of the data for the current month plus the preceding 11 months (running 12 month total), consistent with Condition 7.1.6(i) of Abbott's current Title V permit # 96010010, issued on September 26, 2007. Compliance will be demonstrated according to the compliance calculation methodology and corresponding recordkeeping procedures in Katherine Hodge's April 23, 2008 email to Steven Rosenthal,

including both the body of the email and the attachments, as well as the compliance procedures in Condition 7.1.12(e) of Abbott's current Title V permit # 96010010, issued on September 26, 2007. Finally, Abbott's recordkeeping requirements should also be consistent with the recordkeeping requirements reflected in Katherine Hodge's April 23, 2008 email (attached), including both the body of the email and the attachments. These records would need to be maintained for a period of five years.

If further information is required, please contact Charles E. Matoesian of my staff at 217/524-9453.

Sincerely,

Laurel L. Kroack, Chief
Bureau of Air

Attachments

bcc: Laurel Kroack- letter
Vicky Von Lanken- letter
Jim Ross- letter
AQPS- letter, attachments
Charles Matoesian- letter
Shannon Bilbruck- letter, attachments

From: "Katherine Hodge" <khodge@hdzlaw.com>

To: "Matoesian, Charles" <Charles.Matoesian@Illinois.gov>, "Mahajan, Yoginder" <Yoginder.Mahajan@Illinois.gov>, Steven Rosenthal/R5/USEPA/US@EPA

Cc: "steven.ziesmann" <steven.ziesmann@abbott.com>, "Robert C Wells" <robert.c.wells@abbott.com>, "Lauren C. Lurkins" <llurkins@hdzlaw.com>

Date: 04/23/2008 03:03 PM

Subject: Abbott Laboratories -- Annual Summary of 1999 and 2000 Dryer VOM Emissions

In response to our recent telephone discussion, attached please find detailed supporting data for dryer VOM emissions for 1999 and 2000. The documents "1999_Summary_Dryer_VOM.pdf" and "2000_Summary_Dryer_VOM.pdf" summarize the accumulation of monthly emissions to the annual total. Each file includes emissions from the seven dryers included in the proposed site-specific rule:

Fluid Bed Dryer 1 (Asset No. D0917)
Fluid Bed Dryer 2 (Asset No. D0955)
Fluid Bed Dryer 3 (Asset No. LC933770)
Warm Air Dryer 1 (Asset No. D0964)
Warm Air Dryer 2 (Asset No. D0965)
Warm Air Dryer 3 (Asset No. D0966)
Warm Air Dryer 4 (Asset No. D0967)

For each month, the VOM emission summary lists the total VOM emissions per month for each dryer, and the accumulating total for the year.

In addition to the annual emission summaries, enclosed are one-month samples of the form used to compile and compute the VOM data presented in the summaries. Document "2000_01_FBD_AND_WAD_VOM.pdf" includes two one-page data sheets used to calculate monthly VOM emissions from production data for the three FBDs and the four WADs, respectively, in January of 2000. Each is labeled "0001(alcohol)air.123" in the document header (the number "0001" refers to year 00 and month 01, or January, 2000). The applicable dryers are noted in the upper left corner of the sheet.

For the FBDs, the runs per asset are tabulated by the asset numbers listed above. For the WADs, the racks per dryer are summarized by the dryer number indicated above. In each case, the data summarize for each product (List #) include the pounds of solvent per work order (Solv/WO), number of work orders per month (Number of WOs), and fraction of the solvent from each work order based on

established emission estimating procedures (% Estimated). These data are used to compute the total VOM for monthly manufacturing of the product in question. The runs per asset (for the FBDs) and racks per dryer (for the WADs) are used to distribute the monthly VOM emissions from each list number among the dryers used.

For example, January 2000 VOM from List # 6114 was computed as:

VOM = 344.66 lb solvent/WO * 5 WO/month * 96% Emitted/ 100% Total

= 1,654.4 lb per month; and the emissions from Dryer D-0917 for List # 6114 in pounds per asset were calculated as:

D-0917 = 1,654.4 lb * 10 runs D0917 / (10 + 10 runs for D0917 and D0955)

= 827.18 lb per asset.

Similarly, January 2000 VOM from List # 121 was computed as:

VOM = 835.54 lb solvent/WO * 2 WO/month * 75% Emitted / 100% Total

= 1,253 lb; and the emissions from Dryer 1 for List # 121 in pounds per dryer were calculated as:

Dryer 1 = 1,253 lb solvent * 6 racks Dryer 1 / (6 + 6 + 6 racks for Dryers 1, 2, and 3)

= 417.77 lb per dryer.

The pounds of VOM emitted for each List # for each asset (for the FBDs) and for each dryer (for WADs) were then totaled for the month, and the monthly totals per dryer were transferred from the monthly form to the tracking spreadsheet that included the annual dryer summary discussed above.

Please note that based on the enclosed compilation one small correction needs to be made to the revised Exhibit 3 presented and discussed in the March 7, 2008 Illinois Pollution Control Board (IPCB) hearing. No emissions from FBD No. 3 had been indicated for 1999 in the original or revised Exhibit 3. Upon compilation of the data discussed above, it was noted that one small run with VOM emissions was conducted in FBD No. 3 in 1999. This resulted in emissions of 0.0326 tons (65 pounds) of VOM in the month of July, 1999. This small amount of emissions was inadvertently omitted from the original Exhibit 3 as roundoff error because it was less than 0.1 tons per year, and was not added in when the exhibit was revised for March 7, 2008. The additional 65 pounds of emissions does not change the 1999 annual emission total, the 2-year emission total, or the proposed combined limit for the seven dryers (90 percent of baseline), which are each stated to the nearest 0.1 ton per year in the revised Exhibit 3.

Please let us know if you have any additional questions.

Thank you,

Kathy

Katherine D. Hodge
HODGE DWYER ZEMAN

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Springfield, Illinois 62705-5776
(217) 523-4900
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(See attached file: 2000_Summary_Dryer_VOM.PDF)(See attached file: 1999_Summary_Dryer_VOM.PDF)(See attached file: 2000_01_FBD_AND_WAD_VOM.PDF)

7.1.12 Compliance Procedures

Compliance with the emission limits shall be based on the recordkeeping requirements in Condition 7.1.9 and the emission factors and formulas listed below:

a. Determinations of daily and annual emissions for purposes of 35 IAC 218.480 shall be made using both data on the hourly emission rate (or the emissions per unit of throughput) and appropriate daily and annual data from records of emission unit operation (or material throughput or material consumption data). In the absence of representative test data pursuant to Condition 7.1.7 (see also 35 IAC 218.487) for the hourly emission rate (or the emissions per unit of throughput) such items shall be calculated using engineering calculations, including the methods described in Appendix B of "Control of Volatile Organic Emissions from Manufacturing of Synthesized Pharmaceutical Products" (EPA-450/2-78-029). This Condition shall not affect the Illinois EPA's or the USEPA's authority to require emission tests to be performed pursuant to Condition 7.1.7 (see also 35 IAC 218.487)) [35 IAC 218.480(h)]. Calculations of daily emissions may be performed on a monthly basis.

b. Compliance with Conditions 5.3.2 and 7.1.3(c) is addressed by proper operation of the dust collectors, and filters, as addressed by Condition 7.1.5(d).

c. Compliance with Conditions 7.1.3(b) and 7.1.5(e) is addressed by the applicable provisions of 63.1257(d)(2) or by information or calculations which demonstrate that emission streams that are undiluted and uncontrolled contain less than 50 ppmv HAP, in accordance with the definition of "process vent" in 40 CFR 63.1251.

d. To determine compliance with Conditions 5.6.1, 7.1.3(c), and 7.1.6, PM emissions from the affected pharmaceutical product manufacturing units shall be calculated based on the following:

   i. PM emissions from the Tablet Compressing Area, Spinning Disc, and House Vacuum:

      PM Emissions (lb) = (Amount of Material Recovered from Dust Collector, lb) x [(1 - (Dust Collector Efficiency*, %/100))/(Dust Collector Efficiency*, %/100)]

   ii. PM emissions from Massers, Mills, Kady Mill, Mixers (Grals), Warm Air Dryers, Blenders, and Particle Coating:

PM Emissions (lb) = (Dry Raw Material Usage, lb) x (0.003 lb PM/lb Dry Raw Materials) x [1 - (Dust Collector Efficiency*, %/100)]

iii. PM emissions from Fluid Bed Dryers:

PM Emissions (lb) = (Dry Raw Material Usage, lb) x (0.001 lb PM/lb Dry Raw Materials)

* As specified by manufacturer or vendor of the dust collectors.

e. To determine compliance with Conditions 5.6.1, 7.1.3(d), and 7.1.6, VOM emissions from the affected pharmaceutical product manufacturing units shall be calculated based on the following:

VOM Emissions (lb) = (Total Amount of VOM in Raw Materials, lb) x (Loss Factor, %/100) + (Amount of Cleanup Solvent) x (VOM Content of Cleanup Solvent, %/100)

Where:

Loss Factor is the factor derived from weighing the amount of bulk material present before and after the various processes, determining reduction in weight across the process, and assuming all weight lost was attributable to VOM evaporation. The Loss Factors for the affected pharmaceutical manufacturing units are as follows:

Emission Unit	Loss Factor
Massers (SPM Day, SPM Glenn)	4.0%
Warm Air Dryers	75.0%
Mills (SPM, SPM Sweco, HVM Swecos)	4.0%
Kady Mill	0.5%
Mixers (Gral)	4.0%
Fluid Bed Dryers (FBDs)	96.0%
Blenders	4.0%
Pan Pour	100.0%
Semi-Solid Manufacturing (Static Mixer, Encapsulator)	0.5%
Mix Tanks	0.5%

2000: Annual Summary of AP16A dryer VOM emissions.

Fluid Bed Dryer (FBD) 1 - 3 & Warm Air Dryer (WAD) 1 - 4

AMOUNTS IN TONS, determined by monthly calculations of each dryer

Dryer: / Asset#	FBD #1 (D-0917)	FBD #2 (D-0955)	FBD # 3 LC933770	WAD #1 (D-0964)	WAD #2 (D-0965)	WAD #3 (D-0966)	WAD #4 (D-0967)
2000							
JANUARY TOTAL (Tons)	0.4963	0.4963	0	0.4824	0.4733	0.4824	0.5731
CURRENT MONTH + TOTAL (Tons)	0.4963	0.4963	0	0.4824	0.4733	0.4824	0.5731
FEBRUARY TOTAL (Tons)	0.4963	0.4963	0	0.646	0.945	0.5778	0.6305
CURRENT MONTH + TOTAL (Tons)	0.9926	0.9926	0	1.1284	1.4183	1.0602	1.2036
MARCH TOTAL (Tons)	0	0.0326	0.1663	0.5318	0.2386	0.5936	0.2965
CURRENT MONTH + TOTAL (Tons)	0.9926	1.0252	0.1663	1.6602	1.6569	1.6538	1.5001
APRIL TOTAL (Tons)	0	0	0	0.5778	0.4823	0.2904	0.2223
CURRENT MONTH + TOTAL (Tons)	0.9926	1.0252	0.1663	2.238	2.1392	1.9442	1.7224
MAY TOTAL (Tons)	0	0	0	0.436	0.3338	0.2263	0.2263
CURRENT MONTH + TOTAL (Tons)	0.9926	1.0252	0.1663	2.674	2.473	2.1705	1.9487
JUNE TOTAL (Tons)	0.2482	0.2482	0	0.2272	0.1732	0	0
CURRENT MONTH + TOTAL (Tons)	1.2408	1.2734	0.1663	2.9012	2.6462	2.1705	1.9487
JULY TOTAL (Tons)	0.2482	0.2482	0	0.101	0.101	0.101	0.4051
CURRENT MONTH + TOTAL (Tons)	1.489	1.5216	0.1663	3.0022	2.7472	2.2715	2.3538
AUGUST TOTAL (Tons)	0.3479	0.3147	0	0.4709	0.4639	0.2829	0.1346
CURRENT MONTH + TOTAL (Tons)	1.8369	1.8363	0.1663	3.4731	3.2111	2.5544	2.4884
SEPTEMBER TOTAL (Tons)	0.3309	0.3309	0	0	0.2037	0.2131	0.0564
CURRENT MONTH + TOTAL (Tons)	2.1678	2.1672	0.1663	3.4731	3.4148	2.7675	2.5448
OCTOBER TOTAL (Tons)	0.4136	0.4136	0	0.2334	0.2862	0.0783	0.0949
CURRENT MONTH + TOTAL (Tons)	2.5814	2.5808	0.1663	3.7065	3.701	2.8458	2.6397
NOVEMBER TOTAL (Tons)	0.3309	0.3309	0	0.0831	0.3061	0.3061	0.6612
CURRENT MONTH + TOTAL (Tons)	2.9123	2.9117	0.1663	3.7896	4.0071	3.1519	3.3009
DECEMBER TOTAL (Tons)	0.2482	0.2482	0	0	0	0	0
CURRENT MONTH + TOTAL (Tons)	3.1605	3.1599	0.1663	3.7896	4.0071	3.1519	3.3009

1999: Annual Summary of AP16A dryer VOM emissions.

Fluid Bed Dryer (FBD) 1 - 3 & Warm Air Dryer (WAD) 1 - 4

AMOUNTS IN TONS, determined by monthly calculations of each dryer

Dryer: / Asset#	FBD #1 (D-0917)	FBD #2 (D-0955)	FBD # 3 LC933770	WAD #1 (D-0964)	WAD #2 (D-0965)	WAD #3 (D-0966)	WAD #4 (D-0967)
1999							
JANUARY TOTAL (Tons)	0	0		0.1149	0.2918	0.2059	0.231
CURRENT MONTH + TOTAL (Tons)	0	0		0.1149	0.2918	0.2059	0.231
FEBRUARY TOTAL (Tons)	0.2807	0.2482		0.1083	0.5358	0.6512	0.4889
CURRENT MONTH + TOTAL (Tons)	0.2807	0.2482		0.2232	0.8276	0.8571	0.7199
MARCH TOTAL (Tons)	0.2482	0.2482		0.3903	0.6819	0.6037	0.6794
CURRENT MONTH + TOTAL (Tons)	0.5289	0.4964		0.6135	1.5095	1.4608	1.3993
APRIL TOTAL (Tons)	0.3309	0.3309		0.08	0	0.1844	0.1086
CURRENT MONTH + TOTAL (Tons)	0.8598	0.8273		0.6935	1.5095	1.6452	1.5079
MAY TOTAL (Tons)	0.249	0.249		0.2453	0.3122	0.1776	0.3921
CURRENT MONTH + TOTAL (Tons)	1.1088	1.0763		0.9388	1.8217	1.8228	1.9
JUNE TOTAL (Tons)	0.2482	0.2482	0	0.8403	0.4894	0.6182	0.4886
CURRENT MONTH + TOTAL (Tons)	1.357	1.3245	0	1.7791	2.3111	2.441	2.3886
JULY TOTAL (Tons)	0.579	0.579	0.0326	0.2859	0.3764	0.3573	0.4464
CURRENT MONTH + TOTAL (Tons)	1.936	1.9035	0.0326	2.065	2.6875	2.7983	2.835
AUGUST TOTAL (Tons)	0	0	0	0.4938	0.4496	0.4759	0.4298
CURRENT MONTH + TOTAL (Tons)	1.936	1.9035	0.0326	2.5588	3.1371	3.2742	3.2648
SEPTEMBER TOTAL (Tons)	0.1654	0.1654	0	0.8595	1.1174	0.942	1.0686
CURRENT MONTH + TOTAL (Tons)	2.1014	2.0689	0.0326	3.4183	4.2545	4.2162	4.3334
OCTOBER TOTAL (Tons)	0.2482	0.0827	0	0.3544	0.3067	0.3038	0.2414
CURRENT MONTH + TOTAL (Tons)	2.3496	2.1516	0.0326	3.7727	4.5612	4.52	4.5748
NOVEMBER TOTAL (Tons)	0	0	0	0.3932	0.3511	0.2924	0.3272
CURRENT MONTH + TOTAL (Tons)	2.3496	2.1516	0.0326	4.1659	4.9123	4.8124	4.902
DECEMBER TOTAL (Tons)	0	0	0	0.3527	0.6719	0.5005	0.2548
CURRENT MONTH + TOTAL (Tons)	2.3496	2.1516	0.0326	4.5186	5.5842	5.3129	5.1568

Fluid Bed Dryers (PC 681)

List #	Solv/WO	Number of WOs	Runs/ WO	% Emitted	Runs per Asset D0917	Runs per Asset D0955	Runs per Asset LC933770		Pounds per Asset D0917	Pounds per Asset D0955	Pounds per Asset LC933770
3611	346.40		5	96%				*	None	None	None
4286	67.89		3	96%				*	None	None	None
6114	344.66	5	4+	96%	10	10		*	827.1840	827.1840	0.0000
12044	344.66	1	4+	96%	2	2		*	165.4368	165.4368	0.0000
				TOTAL POUNDS					992.6208	992.6208	0.0000
				TOTAL TONS					0.4963	0.4963	0.0000
							Hours		227.6500	220.4900	
							lb/hr		4.3603	4.5019	ERR

Warm Air Dryers (PC 645)

List #	Pounds Solv/WO	Number of WOs	% Emitted	RACKS Dryer 1	Dryer 2	Dryer 3	Dryer 4		POUNDS OF VOM EMITTED Dryer 1	Dryer 2	Dryer 3	Dryer 4
74	5.94		75%					*	None	None	None	None
121	835.54	2	75%	6	6	6		*	417.7700	417.7700	417.7700	0.0000
B2586	677.83		75%					*	None	None	None	None
3241	11.05		75%					*	None	None	None	None
B3368	689.32		75%					*	None	None	None	None
3925	313.33		75%					*	None	None	None	None
4286	675.39		75%					*	None	None	None	None
4287	320.29		75%					*	None	None	None	None
5726	45.43		75%					*	None	None	None	None
6290	278.51	2	75%		3		3	*	0.0000	208.8825	0.0000	208.8825
6316	908.65	1	75%	6		6	6	*	227.1625	0.0000	227.1625	227.1625
6346	426.47	3	75%	18	18	18		*	319.8525	319.8525	319.8525	0.0000
6667	173.20		75%					*	None	None	None	None
12664	188.00		75%					*	None	None	None	None
69283	946.95	1	75%				8	*	0.0000	0.0000	0.0000	710.2125
TOTAL POUNDS/DRYER								>	964.7850	946.5050	964.7850	1146.2575
TOTAL TONS/DRYER								>	0.4824	0.4733	0.4824	0.5731

TOTAL for ALL Warm Air Dryers: 2.0112

Hours	65.58	50.74	76.08	227.64
lb/hr	14.7116	18.6540	12.6812	5.0354