

BEFORE THE ILLINOIS POLLUTION CONTROL BOARD

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

NOTICE OF FILING

TO: Mr. John Therriault	Kathleen M. Crowley
Assistant Clerk of the Board	Hearing Officer
Illinois Pollution Control Board	Illinois Pollution Control Board
100 West Randolph Street	100 West Randolph Street
Suite 11-500	Suite 11-500
Chicago, Illinois 60601	Chicago, Illinois 60601
(VIA ELECTRONIC MAIL)	(VIA U.S. MAIL)

(PERSONS ON ATTACHED SERVICE LIST)

PLEASE TAKE NOTICE that I have today filed with the Office of the Clerk of the Illinois Pollution Control Board **ENTRY OF APPEARANCE OF LAUREN C. LURKINS, PREFILED TESTIMONY OF DIANE BENO IN SUPPORT OF PROPOSED SITE-SPECIFIC AMENDMENT, and PREFILED TESTIMONY OF ROBERT C. WELLS IN SUPPORT OF PROPOSED SITE-SPECIFIC AMENDMENT**, copies of which are herewith served upon you.

Respectfully submitted,

By: /s/ Katherine D. Hodge
Katherine D. Hodge

Dated: February 22, 2008

Katherine D. Hodge
Lauren C. Lurkins
HODGE DWYER ZEMAN
3150 Roland Avenue
Post Office Box 5776
Springfield, Illinois 62705-5776
(217) 523-4900

CERTIFICATE OF SERVICE

I, Katherine D. Hodge, the undersigned, hereby certify that I have served the ENTRY OF APPEARANCE OF LAUREN C. LURKINS, PREFILED TESTIMONY OF DIANE BENO IN SUPPORT OF PROPOSED SITE-SPECIFIC AMENDMENT, and PREFILED TESTIMONY OF ROBERT C. WELLS IN SUPPORT OF PROPOSED SITE-SPECIFIC AMENDMENT upon:

Mr. John Therriault
Assistant Clerk of the Board
Illinois Pollution Control Board
100 West Randolph Street
Suite 11-500
Chicago, Illinois 60601

via electronic mail on February 22, 2008; and upon:

Kathleen M. Crowley
Hearing Officer
Illinois Pollution Control Board
James R. Thompson Center
100 West Randolph Street, Suite 11-500
Chicago, Illinois 60601

Matthew J. Dunn, Chief
Environmental Bureau North
Office of the Attorney General
69 West Washington Street, Suite 1800
Chicago, Illinois 60602

Charles E. Matoesian, Esq.
Assistant Counsel
Division of Legal Counsel
Illinois Environmental Protection Agency
1021 North Grand Avenue East
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Springfield, Illinois 62794-9276

Office of Legal Services
Illinois Department of Natural Resources
One Natural Resources Way
Springfield, Illinois 62702-1271

by depositing said document in the United States Mail, postage prepaid, in Springfield, Illinois on February 22, 2008.

/s/ Katherine D. Hodge
Katherine D. Hodge

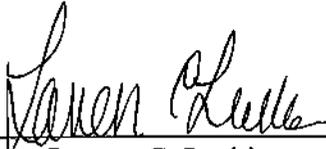
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ENTRY OF APPEARANCE OF LAUREN C. LURKINS

NOW COMES Lauren C. Lurkins, of the law firm HODGE DWYER ZEMAN,
and hereby enters her appearance in this matter on behalf of Abbott Laboratories.

Respectfully submitted,

By: 
Lauren C. Lurkins

Dated: February 22, 2008

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ABOT:003/Fil/EOA – LCL

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**PRE-FILED TESTIMONY OF DIANE BENO,
IN SUPPORT OF PROPOSED SITE-SPECIFIC AMENDMENT**

NOW COMES ABBOTT LABORATORIES, by and through its attorneys,
HODGE DWYER ZEMAN, and pursuant to 35 Ill. Admin. Code § 102.424 and the
Hearing Officer Order, dated January 31, 2008, submits the following Pre-Filed
Testimony of Diane Beno for presentation at the March 7, 2008 hearing scheduled in the
above-referenced matter:

TESTIMONY OF DIANE BENO

My name is Diane Beno. I am the plant manager of the portion of the Abbott
Laboratories facility internally known as Building AP16. The operations contained in
Building AP16 produce intermediate and final pharmaceutical product formulations,
including liquids, tablets and capsules packaged in bottles and blister formats. The
general process flow involves: receipt of raw materials; weighing of ingredients; massing
and granulation of ingredients; compressing granulated product into tablets; coating
tablets or particles; printing symbols onto tablets; and packaging finished products for
distribution.

Over the course of a year, we produce many different products in Building AP16. For example, we produce pharmaceuticals that treat diseases in the field of neuroscience such as epilepsy and bipolar disorder, we make antiviral products for the treatment of AIDS, we manufacture antibiotics to fight infection, we package products that help patients achieve healthy cholesterol levels, and products that improve the lives of people with rheumatoid arthritis, psoriasis and Crohn's disease.

We manufacture our products using batch production processes. In batch production, all of the processing equipment in a process train, including the dryers, manufactures one product at a time. Each batch is completed before the manufacture of the next batch begins. In a typical process, the active and inactive ingredients are combined with a liquid in a process called "massing." This massing process forms uniform granules. The wet granules are dried in tunnel dryers or fluid bed dryers and then further processed into tablets or capsules.

The massing fluid, which is typically either water or ethanol, is evaporated from the solid material in the drying step. If an organic solvent is volatilized from the dryer, it is emitted to the ambient air as volatile organic material ("VOM") or volatile organic compounds ("VOCs"). The quantity of VOM emissions will vary for different products, and is calculated from the quantity of VOM added to the mixture and loss factors defined for the dryers and specified in the Clean Air Act Permitting Program ("CAAPP") Permit for the facility. It is also important to note that the organic solvent currently used in granulation and dried from the granulated mixtures at Building AP16 is ethanol. Ethanol is a VOM, but is not considered a hazardous air pollutant ("HAP"). The proposed site-specific amendment will have no effect on HAP emissions.

Abbott's proposed site-specific amendment for Building AP16 covers four tunnel dryers and three fluid bed dryers. One additional fluid bed dryer, located in Building AP16, is used exclusively for research and development operations and is not involved in the normal operating processes in Building AP16. Therefore, our proposed amendment does not include that dryer.

The tunnel dryers and fluid bed dryers operate on different principles. In the use of tunnel dryers, materials to be dried are spread on trays and placed in a warming chamber or "tunnel" that circulates warm air over and under the trays.

A fluid bed dryer is a large vertical cylindrical shaped vessel with a diffuser that blows warm air up from the bottom of the vessel. The wet intermediate granules are loaded into the dryer and flow upward, suspended in the warm air stream. Abbott has increased its use of fluid bed dryers for recently developed products because they are more efficient and produce a more uniform product than the tunnel dryers. Abbott anticipates increased use of water for the massing fluid in future products. Abbott expects that this preferential use of fluid bed dryers and water-based products will continue. That is, many new products are expected to use fluid bed dryers and water-based formulations, while older products will continue to be manufactured using tunnel dryers.

Batches of specific products are typically manufactured using either one or more tunnel dryers, or one or more fluid bed dryers, but not both, because the technologies are not interchangeable. Individual dryers of the same type can typically be used in combination or interchangeably in many cases, but specific dryers are preferable for

combining with other equipment in a process train to manufacture certain products from an operational efficiency standpoint.

Abbott manufactures its products using batch processes whereby each manufacturing process train and its associated equipment (including the dryers) produces one product at a time in fixed batch sizes. Process trains are designed to accommodate batches of different scales, with some for large batches and others for small batches. Therefore, the scale of a given batch plays an important role in determining which of the dryers will be most efficient. Additionally, in accordance with United States Food and Drug Administration ("US FDA") current Good Manufacturing Practice ("cGMP") guidelines, extensive equipment cleaning is required between batches of different products, resulting in up to three days of lost production time. Therefore, Abbott uses a campaign strategy to continue running batches of the same product consecutively in the process train to minimize this cleaning time.

As currently written, Section 218.480(b) effectively defines a 12-month total VOM limit on each individual dryer. This can limit Abbott's ability to schedule the campaigns of certain products to maximize the efficiency of the processes. In other words, to ensure compliance with the current running 12-month total VOM limit on each dryer, for a particular batch, Abbott may be required to utilize a dryer with low VOM emissions during the last 12 months instead of using the dryer that is the most efficient from a production-scale standpoint. Such selection of dryers, based only on the amount of VOM that has been emitted from an individual dryer during the preceding 12 months, is an inefficient approach to scheduling the use of Abbott's equipment and resources. Additionally, the dryer selected for a given campaign also depends on dryer availability

and other factors. For example, one dryer may be temporarily out of use to allow for cleaning or for unscheduled maintenance requirements. Therefore, the standards, as currently defined, can result in wasted resources by requiring Abbott to dry a small batch of product in our large-scale process train to maintain our equipment-specific VOM limits.

Total annual emissions from a dryer result from the quantity of organic solvent removed from the different products processed in a dryer over a rolling 12-month period. The material is processed in a number of individual campaigns for particular products, each consisting of multiple individual batches. The assignment of a campaign of a particular product to one or more dryers involves a number of operating factors, such as scale and equipment availability, that contribute to the efficiency of manufacturing. The VOM emission threshold effectively acts as an overriding factor that can force a particular production campaign with VOM emissions to be scheduled using equipment that has low enough recent emissions to avoid exceeding a dryer threshold, but that may not otherwise be the optimal or most efficient equipment for the campaign. This scheduling shift increases the operational cost, but results in no environmental benefit, because the actual emissions will be the same as if the campaign would have used the optimal equipment.

In order to ensure Abbott's Lake County manufacturing facilities remain competitive with our national and global competitors, Abbott must continually seek ways of making our manufacturing operations more efficient. The scheduling inefficiency created by Subpart T was identified as one area where improvements in efficiency could be made and is the basis for the proposed amendment. This seems particularly

appropriate, as the business cost created by this inefficiency results in no environmental benefit.

The most efficient method to manufacture Abbott's products in Building AP16 would be to use the dryer that is best suited to the requirements of the production schedule and scale, regardless of the amount of VOM that has been emitted from that dryer in the past 12 months. Provided that the combined VOM emissions from all of the dryers are less than the combined amount allowed under Section 218.480(b), this method of operation would not require an increase in allowable VOM emissions from the Facility. In fact, the proposed amendment would provide Abbott improved production flexibility to utilize the most efficient dryers for a given product, while significantly lowering the total allowed VOM emissions from all the dryers combined.

Thank you. I'll be happy to answer any questions.

* * *

Abbott reserves the right to supplement or modify this pre-filed testimony.

Respectfully submitted,

ABBOTT LABORATORIES,

By: /s/ Katherine D. Hodge
One of its Attorneys

Dated: February 22, 2008

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**PRE-FILED TESTIMONY OF ROBERT C. WELLS,
IN SUPPORT OF PROPOSED SITE-SPECIFIC AMENDMENT**

NOW COMES ABBOTT LABORATORIES, by and through its attorneys,
HODGE DWYER ZEMAN, and pursuant to 35 Ill. Admin. Code § 102.424 and the
Hearing Officer Order, dated January 31, 2008, submits the following Pre-Filed
Testimony of Robert C. Wells for presentation at the March 7, 2008 hearing scheduled in
the above-referenced matter:

TESTIMONY OF ROBERT C. WELLS

My name is Robert C. Wells. I am employed by Abbott Laboratories as Air
Manager for Environmental Support in Abbott's Global Environmental Health and Safety
Department. I provide assistance to Abbott facilities such as Building AP16 with regard
to environmental compliance and managing environmental performance at our facilities
under various air regulations. I have twenty-nine years of experience in air quality
management and the analysis of air emissions, emission control and ambient air quality.
I hold a Bachelor of Science degree in Engineering from Cornell University.

My testimony today concerns technical aspects of Abbott's proposal for a site-
specific amendment to Illinois air regulations at 35 Ill. Admin. Code Part 218.480(b), in

Subpart T of Part 218. Abbott's proposed site-specific amendment concerns provisions impacting the four (4) tunnel dryers (also referred to as warm air dryers) and three (3) fluid bed dryers located in Building AP16 at the Abbott Park facility. The dryers are used to dry mixtures of active pharmaceutical ingredients ("APIs"), excipient ingredients, and massing fluid after they have been processed to produce a solid material with an appropriate granule size. The granulated mixture is then used to manufacture dosage form products (i.e., tablets, capsules, and granules).

The tunnel dryers and fluid bed dryers are currently subject to air regulations for Volatile Organic Material ("VOM") emissions under 35 Ill. Admin. Code Part 218, Subpart T. Under this standard, an individual dryer is required to control VOM emissions if its annual emissions exceed 7.5 tons per year (ton/yr) for a tunnel dryer or 5 ton/yr for a fluid bed dryer.

Emissions from any one dryer vary from year to year. Historically, emissions from each dryer have been significantly below the level that would trigger the requirement for add-on control. Emissions from individual dryers have been held below these limits in part by planning production to distribute VOM-emitting production among the different equipment. Because of the variability, and because of the significant cost to install and operate controls for a dryer that would not be justified, these control thresholds effectively act as the upper limit for annual VOM emissions from an individual dryer.

At this time, production scheduling can be forced to assign one or more dryers to a production campaign based on the dryers' recent past VOM emissions, assigning one or more dryers that have low enough recent emissions to avoid exceeding a dryer threshold,

but that may not otherwise be the optimal or most efficient equipment for the campaign. This scheduling shift increases the operational cost, but results in no environmental benefit, because the actual emissions will be the same as if the campaign would have used the optimal equipment. This scheduling inefficiency was identified as one area where improvements in efficiency could be made, while not increasing the environmental impact of Abbott's operations.

Two environmental management approaches were identified and considered in order to alleviate the inefficiency of the Subpart T operating constraints. One alternative would be to increase the threshold that would trigger the emission control requirement for one or more individual dryers. Such an increase would be justified if the cost of control is greater than what is considered economically achievable for Reasonably Available Control Technology ("RACT"), which was the justification for establishing the original thresholds in Subpart T. A preliminary review of emission control costs indicated that RACT controls would not be justified even at emission thresholds significantly higher than the current limits specified in Subpart T. A second alternative would be to treat the current control threshold as a combined threshold equal to the sum of the individual unit thresholds for the seven manufacturing dryers. This approach would remove a manufacturing constraint without increasing the allowable VOM emissions from the facility.

The above alternatives were first evaluated internally within Abbott. Under the first approach, while Abbott believes that it would be justifiable to increase the emission threshold for one or more dryers, it would also act to increase the facility's allowable emissions, which is not necessary to solve problems of manufacturing efficiency. The

second approach, to re-define the emission threshold as a combined threshold for all dryers, would remedy manufacturing inefficiencies without increasing overall allowable VOM emissions.

Both of these approaches were discussed with the Illinois Environmental Protection Agency ("Illinois EPA"). At that time, Illinois EPA indicated that both Illinois EPA policy and United States Environmental Protection Agency ("USEPA") regulations and guidelines would need to be considered in order for the agency to support a site-specific amendment to 35 Ill. Admin. Code Part 218.

Subsequent discussions among Illinois EPA, USEPA, and Abbott's representatives identified an existing USEPA program that would provide similar operational benefits as the combined threshold approach discussed above. USEPA's Economic Incentive Programs ("EIPs") are described in USEPA's document, *Improving Air Quality With Economic Incentive Programs*, EPA-452/R-01-001, January 2001, which was provided as Exhibit 2 to the Statement of Reasons for the proposed site-specific amendment. Among other programs, this guidance includes provisions for a Source-Specific Emission Cap ("SSEC") as an alternative regulatory approach for emission limits that can regulate emissions with greater flexibility and efficiency than conventional approaches.

Discussions with Illinois EPA and USEPA indicated that a SSEC could allow individual emission limits to be combined into an aggregate cap for the tunnel dryers and fluid bed dryers, provided that the SSEC is set to a level which is less than the units' combined historical actual emissions, rather than equal to current combined allowable emissions. Both Illinois EPA and USEPA indicated that a SSEC EIP would be an

acceptable method to address the applicability provisions of Section 218.480(b) with respect to Abbott's tunnel dryers and fluidized bed dryers.

Under the current regulatory standard, the combined allowable emission threshold for Abbott's dryers is 45 ton/yr of VOM emissions. This is based on the sum of the allowable emissions for four tunnel dryers at 7.5 ton/yr each and three fluid bed dryers at 5.0 ton/yr each. A SSEC within the EIPs would typically require allowable emissions to be reduced below a baseline level defined by the historical actual emissions for the units. Under USEPA guidelines, historical actual emissions are defined as the highest actual emissions from any 2-year period within the last 10 years of operation. In addition, the EIP requires a demonstration of environmental benefit, which can be achieved by setting an emission limit 10 percent below the baseline emissions. Such a program would be more constraining than either of the two alternatives proposed by Abbott. However, while either of Abbott's original alternatives would likely be approvable, it was recognized that it would be more administratively efficient to work within the EIPs framework if it were otherwise acceptable to achieve Abbott's goals.

Abbott reviewed its historical actual emissions to determine if a SSEC would be appropriate. Actual emissions from the seven dryers are shown in Exhibit 3 of the Statement of Reasons for this site-specific amendment. In accordance with USEPA guidance, the baseline emissions for Building AP16 were calculated to be 22.9 ton/yr based on the historical actual emissions from the highest 2-year period of the past 10 years. Thus, in order to demonstrate environmental benefit as described in the EIP guidance, the total allowable combined emissions from the seven dryers under the

proposed SSEC would need to be set at a level 10 percent lower than the calculated baseline emissions, or 20.6 ton/yr of VOM.

In comparison with this prospective limit, the current combined allowable VOM emission rate, based on the individual thresholds for each of the seven dryers, is 45 ton/yr. Although Abbott could operate at this emission level if needed for operations, its historical actual emissions have consistently been lower than the current combined allowable emissions for the seven dryers. Thus, the current allowable combined emission rate is higher than what Abbott is proposing under the amended site-specific standard. Abbott considers the flexibility to shift production among the dryers to be more important than the ability to operate with current maximum overall emissions. Therefore, the principal requirement for a SSEC under the EIP, a combined allowable emission threshold lower than historical actual emissions, would be an acceptable alternative to Abbott.

In order to ensure that the proposed site-specific amendment to 35 Ill. Admin. Code § 218.480(b) is consistent with USEPA guidance regarding EIPs, and to realize the administrative benefit of a program that is acceptable to all prospective parties, the program must satisfy three fundamental principles of USEPA's EIP program: integrity, equity and environmental benefit. These are defined and discussed in USEPA's *Improving Air Quality with Economic Incentive Program*. See Exhibit 2, Statement of Reasons. Consistency with each of these three principles is discussed separately below.

The principle of integrity consists of four elements: emissions must be *surplus*, *quantifiable*, *enforceable*, and *permanent*. Note that these terms have specific meanings, and are different for a SSEC than for other programs addressed by the policy. *Id.* at 35.

- Emissions are surplus because the baseline for the prospective SSEC for the seven dryers is based on the historical actual emissions for these units, and because the program will reduce emissions below this baseline.
- Emissions are quantifiable because the calculation of both baseline emissions and future emissions under the SSEC is based on a mass balance for a solvent evaporation process with VOM among the materials used. A mass-balance calculation is considered to be a very reliable methodology for quantifying VOM emissions on a 12-month average basis. The methodology for quantifying emissions from the dryers is already well documented in the facility's CAAPP Permit.
- Emissions are enforceable because the program is to be incorporated into 35 Ill. Admin. Code Part 218, approved by USEPA as part of Illinois' State Implementation Plan for ozone attainment, and incorporated into the facility's CAAPP Permit as an applicable requirement. Enforcement will be based on the same program that is now in place in the CAAPP Permit, where emissions are tracked by mass-balance emission calculations based on production records.
- Emissions are permanent because the site-specific amendment to 35 Ill. Admin. Code Part 218 will memorialize the conditions.

The principle of equity is evaluated to ensure that the EIPs program does not result in "an uneven distribution of emissions or ... effects." Id. at 46. This program is not of concern for equity issues for three reasons.

- This program focuses exclusively on VOM emissions from one particular facility. Therefore, there is no concern for impacts in one area that must be balanced equitably with reductions in another area. In addition, the EIP will result in lower emissions than the historic actual emissions for the units in the sole area of impact. Therefore, there will be no area of increased environmental impact that must be balanced against an overall impact reduction. In concurrence, USEPA guidance indicates that equity issues are typically not of concern for a single-site SSEC program. Id. at 50.
- Emissions of VOM have environmental effects on a regional scale rather than a localized impact. Also, the overall impact of the program will be positive because both allowable and historical actual emissions will be reduced.

The principle of environmental benefit is satisfied by the intention for the program to reduce emissions 10 percent below historical actual levels. While other

demonstrations of benefits may be appropriate, the 10 percent emission reduction criteria is clearly defined by USEPA as appropriate for demonstration of environmental benefit. Id. at 51. Illinois EPA and USEPA both agreed that Abbott's proposal met the criteria for a SSEC EIP.

In summary, the proposed site-specific amendment will result in significant environmental benefits. Maximum future *allowable* emissions of 20.6 ton/yr from the seven dryers will be 10 percent below the historical *actual* emissions determined by USEPA criteria (22.9 ton/yr). Future actual combined emissions from the seven dryers will be well below what is currently allowed for the units (45 ton/yr).

At the same time, the proposed site-specific amendment will provide increased operational efficiency and flexibility that will be valuable to Abbott in addressing our national and global competitors. As importantly to the overall result, Abbott's increased flexibility can be achieved without relaxing the stringency of the current emission control thresholds.

I would like to thank the Board for its time and attention in considering our proposal and my testimony. I would also like to thank the Illinois EPA for working with Abbott to identify a practical site-specific amendment for greater regulatory efficiency. I would be happy to answer any questions.

* * *

Abbott reserves the right to supplement or modify this pre-filed testimony.

Respectfully submitted,

ABBOTT LABORATORIES,

By: /s/ Katherine D. Hodge
One of its Attorneys

Dated: February 22, 2008

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