UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION II
290 BROADWAY
NEW YORK, NEW YORK 10007-1866

October 3, 2008

Debra J. Jezouit, Esq.
Baker Botts L.L.P.
The Warner
1299 Pennsylvania Ave., NW
Washington, DC 20004-2400

In the Matter of: Bristol-Myers Squibb Company - Docket No. CAA-02-2008-1212

Dear Ms. Jezouit:

Enclosed, please find a copy of the executed Consent Agreement and Final Order (CAFO) for your records. Note that the terms of the CAFO are now in effect.

If you have any questions, feel free to contact me at (212) 637-3201.

Sincerely,

Evans J. Stamataky, Esq.
Assistant Regional Counsel

Enclosure

cc: K. Maples, EPA, w/original and copy
K. Eng, 2DECA-ACB
M. Ghaffari, 2DECA-ACB, w/enc.
J. Menczel, 2DECA-CAP, w/enc.
B. Edwards, OCFO/OFS/CFC, w/enc.
E. Stamataky, 2ORC-AIR, w/enc.

CERTIFICATE OF SERVICE

In re: **Bristol-Myers Squibb Company - CAA-02-2008-1212**

I certify that I have this day, October 3, 2008, caused to be sent the foregoing fully executed CONSENT AGREEMENT AND FINAL ORDER, bearing the above-referenced docket number, in the following manner to the respective addressees below:

Original and One Copy by Hand To:

Karen Maples
Regional Hearing Clerk
U.S. Environmental Protection
Agency – Region 2
Office of Regional Counsel
290 Broadway – 16th Floor
New York, New York 10007

Copy by Certified Mail
Return Receipt Requested To:

Debra J. Jezouit, Esq.
Baker Botts, L.L.P.
The Warner
1299 Pennsylvania Avenue, N.W.
Washington, D.C. 20004-2400

Dated: October 3, 2008
New York, New York

Orelia Lewis, Secretary

Contact: Michelle Angel (Angel.michelle@epa.gov). All emailed documents should include a cc: to AcctsReceivable.CINWD@epa.gov

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Region 2

In the Matter of Bristol-Myers Squibb Company Humacao, Puerto Rico Facility and Barceloneta, Puerto Rico Facility Respondent In a proceeding under Section 113(d) of the Clean Air Act	CONSENT AGREEMENT AND FINAL ORDER CAA-02-2008-1212

CONSENT AGREEMENT

Preliminary Statement

The United States Environmental Protection Agency (EPA) issues this Consent Agreement and Final Order (CAFO), under the authority of 42 U.S.C. § 7401 et seq the Clean Air Act (CAA or Act), 42 U.S.C. § 7413(d), Section 113(d), and 40 C.F.R. Part 22 (Consolidated Rules of Practice). The Complainant in this matter is the Director of the Division of Enforcement and Compliance Assistance, EPA Region 2, who is duly delegated the authority to issue CAA Section 113(d) Consent Agreements on behalf of EPA Region 2, which includes the State of New York, the State of New Jersey, the

Commonwealth of Puerto Rico, and the Territory of the U.S. Virgin Islands. The Regional Administrator of EPA Region 2 is duly delegated the authority to execute CAA Section 113(d) Final Orders.

On February 6, 2008, the U.S. Department of Justice (DOJ) granted EPA's request for a waiver of the CAA Section 113(d) 12-month limitation on EPA's authority to initiate an administrative action against Bristol-Myers Squib Company (BMS or Respondent).

In 2005, BMS voluntarily undertook an environmental audit (Humacao Audit), at a pharmaceutical manufacturing facility (Humacao Facility) it owned and operated in Humacao Puerto Rico. Also in 2005, BMS voluntarily undertook an environmental audit (Barceloneta Audit), at a pharmaceutical manufacturing facility (Barceloneta Facility) it owned and operated in Barceloneta, Puerto Rico. Throughout the voluntary audit process, Respondent disclosed to Complainant violations of the maximum available control technology (MACT) standards, 40 C.F.R. Part 63, Subpart A (General MACT), Subpart GGG (Pharmaceutical MACT), and subpart EEE (Hazardous Waste Combustor MACT), all of which were promulgated pursuant to Sections 112 and 114 of the Act. In its disclosures to Complainant, Respondent sought 100% mitigation of gravity-based penalties, as provided by EPA's "Incentives for Self-Policing: Discovery, Disclosure, Correction and Prevention of Violations," (Audit Policy). 65 Fed. Reg. 19,618 (April 11, 2000).

On July 31, 2007, EPA determined that the Humacao Audit and the Barceloneta Audit satisfied all of the Audit Policy conditions. Under these circumstances, the Audit Policy directs EPA not to seek any gravity-based penalties. However, in accordance

with the Audit Policy, Respondent is liable for the monetary penalty associated with the economic benefits realized through the violations it disclosed. Respondent's economic benefit liabilities are resolved through this CAFO.

40 C.F.R. § 22.13(a) and (b) provide the general procedures for settlement of administrative enforcement actions provided they are commenced in accordance with § 22.13(a) and (b). Pursuant to § 22.13(a), any proceeding subject to the Consolidated Rules of Practice is commenced by filing a complaint with the Regional Hearing Clerk. However, pursuant to § 22.13(b) a proceeding may be simultaneously commenced and concluded, by the issuance of a CAFO, provided EPA issues the CAFO pursuant to § 22.18(b)(2) and (3).

Pursuant to § 22.18(b)(2), where an action is commenced pursuant to § 22.13(b), the consent agreement shall contain the elements described in § 22.14(a)(1)-(3) and (8). Pursuant to § 22.18(b)(3), no settlement or consent agreement shall dispose of any proceeding under the Consolidated Rules of Practice without a final order that ratifies the parties consent agreement either from the Regional Judicial Officer or Regional Administrator or, in a proceeding commenced at EPA Headquarters, from the Environmental Appeals Boards.

In accordance with 40 C.F.R. § 22.18(b), and § 22.13(b), EPA and Respondent have agreed to simultaneously commence and resolve an action for the economic benefit liability that Respondent realized as a result of the violations disclosed in its two environmental audits.

For purposes of this proceeding, and to avoid the expense of protracted litigation, Respondent: (1) admits that EPA has jurisdiction over the subject matter alleged in this

Consent Agreement; (2) neither admits nor denies specific factual allegations contained in this Consent Agreement; (3) consents to the terms of agreement set forth in this Consent Agreement; and (4) consents to the issuance of the attached Final Order.

Statutory and Regulatory Background

1. Section 302(e) of the Act defines the term "person" as an individual, corporation, partnership, association, state municipality, political subdivision of a State, and any agency, department, or instrumentality of the United States and any officer, agent, or employee thereof.

2. Section 112(d) of the Act requires EPA to promulgate regulations establishing emission standards for each category or subcategory of major and area sources listed for regulation pursuant to § 112(c) of the Act.

3. Section 114(a)(1) of the Act authorizes the Administrator to require owners or operators of emission sources to submit specific information regarding facilities, establish and maintain records, make reports, sample emission points, and to install, use and maintain such monitoring equipment or methods in order to determine whether any person is in violation of the Act.

4. Pursuant to §§ 112 and 114 of the Act, the Administrator of EPA promulgated 40 C.F.R. Part 63, Subpart A (General MACT). 59 Fed. Reg. 12430 (March 16, 1994).

5. Pursuant to §§ 112 and 114 of the Act, EPA promulgated 40 C.F.R Part 63, Subpart GGG (Pharmaceutical MACT). 63 Fed. Reg. 50326 (September 21, 1998).

6. 40 C.F.R. § 63.2 defines "existing source" as any affected source that is not a new source.

7. 40 C.F.R. § 63.2 defines "owner or operator" as any person who owns, leases, operates, controls, or supervises a stationary source.

8. Pursuant to 40 C.F.R. § 63.1(4)(i), each relevant standard in 40 C.F.R. Part 63 must identify explicitly whether each provision in the General MACT is or is not included in each relevant standard.

9. Pursuant to 40 C.F.R. § 63.1250(a), except as provided by 40 C.F.R. § 63.1250(d), an affected source subject to the Pharmaceutical MACT is any pharmaceutical manufacturing operation, as defined in § 63.1251, that:

a. manufactures a pharmaceutical product, as defined in 40 C.F.R. § 63.1251;

b. is located at plant site that is a major source, as defined in Section 112(a) of the Act; and

c. processes, uses or produces any HAP.

10. Pursuant to 40 C.F.R. § 63.1250(b), a new affected source subject to the Pharmaceutical MACT and to which the requirements for new sources apply is: an affected source, for which construction or reconstruction commenced after April 2, 1997 and the standard was applicable at the time of construction or reconstruction; or a pharmaceutical manufacturing process unit (PMPU) dedicated to manufacturing a single product that has the potential to emit 10 tons per year of any one HAP or 25 tons per year of combined HAP for which construction commenced after April 2, 1997 or reconstruction commenced after October 21, 1999.

11. Pursuant to 40 C.F.R. § 63.1250(c), Table 1 of the Pharmaceutical MACT specifies the provisions of the General MACT that apply to an owner or operator of an affected source subject to the Pharmaceutical MACT and provides comments on the General MACT requirements.

12. 40 C.F.R. § 63.1251 defines pharmaceutical manufacturing operation as the facility wide collection of PMPU and any other equipment such as heat exchanger systems, wastewater and waste management units, or cooling tower that are not associated with the individual PMPU, but that are located at a facility for the purpose of manufacturing pharmaceutical product and are under common control.

The following regulatory provisions concern BMS' self-disclosed violations, regarding the Humacao Facility, that are subject to penalties for economic benefit:

13. Pursuant to 40 C.F.R. § 63.6(e)(1)(i), which is listed as an applicable requirement in Table 1 of the Pharmaceutical MACT, at all times, including periods of startup, shutdown, and malfunction, the owner or operator must operate and maintain any affected source, including associated air pollution control equipment and monitoring equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions.

14. Pursuant to 40 C.F.R. § 63.6(e)(3)(i), which is listed as an applicable requirement in Table 1 of the Pharmaceutical MACT, the owner or operator of an affected source must develop a written startup, shutdown, and malfunction plan that describes, in detail, procedures for operating and maintaining the source during periods of startup, shutdown, and malfunction; and a program of corrective action for

malfunctioning process, air pollution control, and monitoring equipment used to comply with the relevant standard.

15. Pursuant to 40 C.F.R. § 63.1252(b)(1), the owner or operator of a closed-vent system that contains bypass lines that could divert a vent stream away from a control device used to comply with the requirements in 40 C.F.R. §§ 63.1253, 63.1254, and 63.1256 must comply with the monitoring requirements of Table 4 of the Pharmaceutical MACT and paragraph (b)(1) or (2) of 40 C.F.R. § 63.1252.

16. Pursuant to 40 C.F.R. § 63.1259(i), the owner or operator of an affected source must keep records specified in paragraphs (i)(1) through (9) of 40 C.F.R. § 63.1259.

17. Pursuant to 40 C.F.R. § 63.1259(i)(1), an owner or operator must keep a record of each waste management unit inspection required by 40 C.F.R. § 63.1256(b) through (f) that was performed.

The following regulatory provisions concern BMS' self-disclosed violations, regarding the Barceloneta Facility, that are subject to penalties for economic benefit:

18. 40 C.F.R. § 63.6(e)(1)(i). See paragraph 13, above.

19. Pursuant to 40 C.F.R. § 63.8 (d)(2), which is listed as an applicable requirement in Table 1 of the Pharmaceutical MACT, the owner or operator of an affected source that is required to use a continuous monitoring system (CMS) and is subject to the monitoring requirements of 40 C.F.R. § 63.8 and a relevant standard, must develop and implement a CMS quality control program.

20. Pursuant to 40 C.F.R. § 63.10(e)(3)(vi)(G), which is listed as an applicable requirement in Table1 of the Pharmaceutical MACT, the owner or operator must submit

a summary report containing the date of the latest CMS, certification or audit for the HAPs monitored at each affected source.

21. 40 C.F.R. § 63.1252(b)(1). See paragraph 15, above.

22. Pursuant to 40 C.F.R.§ 63.1256(g)(1), an owner or operator of an existing affected source must comply with an appropriate control option when a wastewater stream at the source exceeds or is designated to exceed the concentration and load criteria specified in paragraph 40 C.F.R. § 63.1256(g)(a)(1)(i)(A), (B) or (C).

23. Pursuant to 40 C.F.R. § 63.1257(b), when testing is conducted to measure emissions from an affected source, an owner or operator of an affected source must use the test methods specified in paragraphs (b)(1) through (10) of 40 C.F.R. § 63.1257.

24. Pursuant to 40 C.F.R. § 63.1257(d), an owner or operator of an affected source complying with the process vent standards specified in 40 C.F.R. § 63.1254, must demonstrate initial compliance using the procedures described in paragraphs (d)(1) through (d)(4) of 40 C.F.R. § 63.1257.

25. Pursuant to 40 C.F.R. § 63.1258(b)(1)(ii), for affected sources using liquid scrubbers, the owner or operator must rneasure and record the scrubber liquid flow rate or pressure drop every 15 minutes during which the scrubber is functioning in achieving the Hazardous Air Pollutant (HAP) removal required by 40 C.F.R. § 63.1252.

26. Pursuant to 40 C.F.R. § 63.1258(g)(1), for each specified wastewater management unit, including wastewater tanks, the owner or operator must comply with the semiannual inspection requirement specified in Table 7 of the Pharmaceutical MACT.

27. Pursuant to 40 C.F.R. § 63.1259(a)(1), each owner or operator of an affected source must keep copies of all records and reports required by the Pharmaceutical MACT for at least 5 years, as specified in 40 C.F.R. § 63.10(b)(1), which is listed as an applicable requirement in Table1 of the Pharmaceutical MACT.

28. Pursuant to 40 C.F.R. § 63.1259(b)(1), the owner or operator of an affected source must keep up-to-date and readily available records of each measurement of a control device operating parameter rnonitored in accordance with 40 C.F.R. § 63.1258 and each measurement of a treatment process parameter monitored in accordance with 40 C.F.R. § 63.1258(g)(2) and (3).

29. Pursuant to 40 C.F.R. § 63.1259(g), the owner or operator transferring an affected wastewater stream or residual removed from an affected wastewater stream in accordance with 40 C.F.R. § 63.1256 (a)(5) must keep a record of the notice sent to the treatment operator stating that the wastewater steam or residual contains organic HAP, required to be managed and treated in accordance with the provisions of the Pharmaceutical MACT.

30. 40 C.F.R. § 63.1259(i)(1). See paragraph 17, above.

31. Pursuant to 40 C.F.R. § 63.1260(i)(2), any time an owner or operator of an affected source takes an action that is not consistent with the procedures specified in the affected source's startup, shutdown, and malfunction (SSM) plan, the owner or operator must submit immediate startup, shutdown and malfunction reports, as specified in 40 C.F.R. § 63.10(d)(5)(ii), which is listed as an applicable requirement in Table 1 of the Pharmaceutical MACT.

Findings of Fact

32. Respondent is engaged in the discovery, development, manufacturing, and distribution of prescription pharmaceutical products and other consumer healthcare products.

33. Respondent is a corporation incorporated in the State of Delaware.

34. At all times relevant to this Consent Agreement, Respondent owned and operated the Humacao Facility, a pharmaceutical manufacturing facility located at State Road 3, Km. 77.5, Humacao, Puerto Rico.

35. At all times relevant to this Consent Agreement, Respondent owned and operated the Barceloneta Facility, a pharmaceutical manufacturing facility located at State Road 2, Km. 56.4, Barceloneta, Puerto Rico.

36. On May 12, 2005, Respondent informed Complainant that on March 15, 2005 Respondent commenced the Humacao and Barceloneta Audits to determine compliance with the Pharmaceutical MACT.

37. On May 12, 2005, Respondent also identified violations discovered during the Humacao Audit.

38. In a June 2, 2005 letter, Respondent identified violations discovered during the Humacao Audit.

39. In a follow-up June 22, 2005 letter, Respondent discussed the Humacao Audit and asserted compliance with the Audit Policy.

40. In its June 22, 2005 submittal, Respondent provided a list and described the violations discovered during the Humacao Audit. Regulatory provisions that BMS indicated it had violated, subject to economic benefit penalties are: 40 C.F.R. §§ 63.6,

63.1252 and 63.1256. In order to allege violations, EPA has provided a concise statement of the factual basis for each of these disclosures in the Conclusion of Law section of this CAFO.

41. Also in its June 22, 2005 submittal, BMS: (1) summarized and enumerated each of the violations discovered during the Humacao Audit; (2) identified emissions levels associated with each of the violations, and (3) presented the results of its calculations (derived using EPA's Economic Benefit from Delayed Compliance (BEN) model 4.2) of the monetary value of the economic benefit realized as a result of the violations.

42. Respondent provided a total calculation of $6,594, for the monetary economic benefit of its noncompliance with 40 C.F.R. §§ 63.6, 63.1252 and 63.1256.

43. EPA agreed with Respondent with respect to violations for which the Humacao Facility should be assessed penalties for economic benefit; however, utilizing a more recent BEN model (4.3), EPA calculated the total monetary economic benefit for these violations to be $5,421.

44. In a July 8, 2005 letter, Respondent discussed the Barceloneta Audit and asserted compliance with the Audit Policy.

45. In its July 8, 2005 submittal, BMS listed and described the violations discovered during the Barceloneta Audit. Regulatory provisions that BMS indicated it had violated, that are subject to economic benefit penalties, are: 40 C.F.R. §§ 63.6, 63.8, 63.10, 63.1252, 63.1256, 63.1257, 63.1258, 63.1259, and 63.1260. In order to allege violations, EPA has provided a concise statement of the factual basis for each of these disclosures in the Conclusion of Law section of this CAFO.

46. Also in its July 8, 2005 submittal, BMS: (1) summarized and enumerated each of the violations discovered during the Barceloneta Audit; (2) identified emissions levels associated with each of the violations, and (3) presented the results of its calculations (derived using EPA's Economic Benefit from Delayed Compliance (BEN) model 4.2) of the monetary value of the economic benefit realized as a result of the violations.

47. Respondent provided a total calculation of $81,981, for the monetary economic benefit of its noncompliance with 40 C.F.R. §§ 63.6, 63.8, 63.10, 63.1252, 63.1256, 63.1257, 63.1258, 63.1259 and 63.1260.

48. EPA agreed with Respondent with respect to violations for which the Barceloneta Facility should be assessed penalties for economic benefit; however, utilizing a more recent version (4.3) of the BEN model, EPA calculated the total monetary economic benefit for these violations to be $ 61,349.

49. In making its disclosures regarding both the Humacao and Barceloneta Facilities, in accordance with the Audit Policy, Respondent specifically certified to the following nine (9) conditions of the Audit Policy:

i. the violations were discovered through an audit or through a compliance management system reflecting due diligence in preventing, detecting and correcting violations;

ii. the violations were discovered voluntarily;

iii. the initial violations were disclosed to EPA promptly and in writing and subsequent disclosures were also prompt and in writing

iv. the violations were disclosed prior to commencement of an agency inspection or investigation, notice of a citizen suit, filing of a complaint by a third party, reporting of the violations by a "whistle blower" employee, or imminent discovery by a regulatory agency;

v. the violations have been corrected and the Respondent is, to the best of its knowledge and belief, in full compliance with CAA §§ 112 and 114, and the implementing regulations, with respect to the violations set forth in this Agreement;

vi. appropriate steps have been taken to prevent a recurrence of the violations;

vii. Respondent has no knowledge that violations other than those covered in this Agreement (or closely related violations), have occurred within the past three years at the same facilities; nor are the specific violations that are the subject of this Agreement part of a pattern of violations by the entity's parent organization which have occurred over the past five years;

viii. the violations have not resulted in serious actual harm nor presented an imminent and substantial endangerment to human health or the environment and they did not violate the specific terms of any judicial or administrative Final Order or Agreement; and

ix. Respondent has cooperated as requested by EPA.

50. On July 31, 2007, EPA determined that the Humacao Audit and the Barceloneta Audit satisfied all of the Audit Policy conditions.

Conclusions of Law

51. In concurrence with the Findings of Fact, EPA finds that Respondent is a person within the meaning of CAA § 302(e), 42 U.S.C. § 7602(e), and is therefore subject to the provisions of the Act and regulations promulgated under the Act.

52. At all times relevant to this Consent Agreement, the following statutory and regulatory provisions applied to the Humacao Facility and the Barceloneta Facility: the Clean Air Act: 42 U.S.C. § 7401 et seq., including §§ 112 and 114 of the Act the General MACT and the Pharmaceutical MACT.

With respect to Respondent's Humacao Facility:

53. In concurrence with the Findings of Fact and Respondent's disclosures, referenced into the Findings of Fact, EPA finds that during the period of time relevant to this Consent Agreement, Respondent was the owner and operator of the Humacao Facility, within the meaning of 40 C.F.R. § 63.2.

54. In concurrence with the Findings of Fact and Respondent's disclosures, referenced into the Findings of Fact, EPA finds that the Humacao Facility is a pharmaceutical manufacturing facility and is subject to the Sections 112 and 114 of the Act, and the General MACT and the Pharmaceutical MACT.

55. In concurrence with the Findings of Fact and Respondent's disclosures, referenced into the Findings of Fact, EPA finds that Respondent violated 40 C.F.R. § 63.6(e)(1)(i) by failing to operate and maintain an affected source, including associated air pollution control equipment and monitoring equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions (1) during excess emission events caused by low water levels and kerosene flow at the boiler/deaerator; and (2) during a malfunction event resulting in venting of excessive emissions at Building 3.

56. In concurrence with the Findings of Fact and Respondent's disclosures, referenced into the Findings of Fact, EPA finds that Respondent violated 40 C.F.R. § 63.6(e)(3)(i) by not addressing the Facility's switching from one thermal oxidizer unit to another thermal oxidizer in its SSM plan.

57. In concurrence with the Findings of Fact and Respondent's disclosures, referenced into the Findings of Fact, EPA finds that Respondent violated 40 C.F.R. § 63.1252(b)(1) by failing to monitor a bypass valve.

58. In concurrence with the Findings of Fact, Respondent's disclosures, referenced into the Findings of Fact and discussions subsequent to the disclosures, EPA finds that Respondent violated 40 C.F.R. § 63.1259(i) by failing to keep records of initial and semiannual inspections of waste water drains required by 40 C.F.R. § 63.1256(e).

59. In concurrence with the Findings of Fact and Conclusions of Law set forth above, EPA finds that Respondent's violations of 40 C.F.R. §§ 63.6(e), 63.1252(b)(1), 63.1259(i) are violations of Sections 112 of the Act.

60. In concurrence with the Findings of Fact and Conclusions of Law set forth above, EPA finds that Respondent's violations of 40 C.F.R. § 63.1259(i), are also violations of Section 114 of the Act.

With respect to Respondent's Barceloneta Facility:

61. In concurrence with the Findings of Fact and Respondent's disclosures, referenced into the Findings of Fact, EPA finds that during the period of time relevant to this Consent Agreement, Respondent was the owner and operator of the Barceloneta Facility, within the meaning of 40 C.F.R. § 63.2.

62. In concurrence with the Findings of Fact and Respondent's disclosures, referenced into the Findings of Fact, EPA finds that the Barceloneta Facility is a

pharmaceutical manufacturing facility, subject to the Sections 112 and 114 of the Act, and the General MACT and the Pharmaceutical MACT.

63. In concurrence with the Findings of Fact, and Respondent's disclosures referenced into the Findings of Fact, EPA finds that Respondent violated 40 C.F.R. § 63.6(e) by failing to operate the Facility in a manner consistent with good air pollution control practices for minimizing emissions when it experienced: (1) fuel oil burner problems; (2) power failures; (3) low water levels in a boiler or de-aerator; and when it (4) switched to backup power for power interruptions lasting longer than 30 minutes; and when it (5) continued to operate air strippers when its thermal oxidizers were off-line to avoid direct emissions of uncontrolled HAPs.

64. In concurrence with the Findings of Fact and Respondent's disclosures, referenced into the Findings of Fact, EPA finds that Respondent violated 40 C.F.R. § 63.8(d) by failing to update the Facility's quality assurance/quality control plan, thereby operating with an inadequate quality assurance/quality control program.

65. In concurrence with the Findings of Fact and Respondent's disclosures, referenced into the Findings of Fact, EPA finds that Respondent violated 40 C.F.R. § 63.1258 (g) by not retaining records of inspections of waste management units.

66. In concurrence with the Findings of Fact and Respondent's disclosures, referenced into the Findings of Fact, EPA finds that Respondent violated 40 C.F.R. § 63.10(e)(3)(vi)(G) by failing to report the dates in the CMS certification of three annual calibrations of the second flow meter on the Andersen Scrubber.

67. In concurrence with the Findings of Fact and Respondent's disclosures, referenced into the Findings of Fact, EPA finds that Respondent violated 40 C.F.R. § 63.1252(b) by failing to monitor a hydrogenated bypass value.

68. In concurrence with the Findings of Fact, Respondent's disclosures, referenced into the Findings of Fact and discussions subsequent to the disclosures, EPA finds that Respondent violated 40 C.F.R. § 63.1256(g)(1) by exceeding concentrations or load criteria designated in the Notice of Compliance Status report for the Barceloneta Facility.

69. In concurrence with the Findings of Fact and Respondent's disclosures, referenced into the Findings of Fact, EPA finds that Respondent violated 40 C.F.R. § 63.1257(b) by failing to utilize prescribed test methods specified in 40 C.F.R. § 63.1257(b) to monitor emissions.

70. In concurrence with the Findings of Fact and Respondent's disclosures, referenced into the Findings of Fact, EPA finds that Respondent violated 40 C.F.R. § 63.1259 by failing to: (1) retain flow monitoring data for each flow meter on the Andersen Scrubber; (2) maintain all records of bypass monitoring data; (3) comply with recordkeeping requirements concerning the semiannual inspections of waste management units; and (4) refer to the Pharmaceutical MACT in notifications for wastewater off-site shipments.

71. In concurrence with the Findings of Fact and Respondent's disclosures, referenced into the Findings of Fact, EPA finds that Respondent violated 40 C.F.R. § 63.1260(i) by failing to report deviations from the SSM plan.

72. In concurrence with the Findings of Fact and Conclusions of Law set forth above, EPA finds that Respondent's violations of 40 C.F.R. §§ 63.6(e) and § 63.1256(g)(1) are violations of Sections 112 of the Act.

73. In concurrence with the Findings of Fact and Conclusions of Law set forth above, EPA finds that Respondent's violations of 40 C.F.R. §§ 63.8(d), 63.10(e)(3)(vi)(G), 63.1252(b), 63.1257(b), 63.1259 and 63.1260(i) are violations of Sections 112 and 114 of the Act.

CONSENT AGREEMENT

Based on the foregoing, and in accordance with federal laws and regulations, it is agreed that:

74. Respondent shall pay a civil penalty, pursuant to Section 113(d) of the Act, for the economic benefit derived from violations alleged in this CAFO, of sixty six thousand seven hundred seventy dollars ($66,770,), either by cashiers' or certified check, within thirty (30) days from the date of issuance of the attached Final Order (Due Date). Respondent shall: (1) clearly type or write the docket number (CAA-02-2008-1212) on the check to ensure proper payment; (2) make the check payable to the order of "Treasurer, United States of America;" and (3) send the check to:

U.S. Environmental Protection Agency
Fines and Penalties
Cincinnati Finance Center
P.O. Box 979077
St. Louis, MO 63197-9000

Respondent shall send notice of payment to the following individuals:

Kenneth Eng, Air Compliance Branch Chief
Division of Enforcement and Compliance Assistance
U.S. Environmental Protection Agency - Region 2
290 Broadway - 21st Floor
New York, New York 10007

and

Flaire Hope Mills, Air Branch Chief
Office of Regional Counsel
U.S. Environmental Protection Agency - Region 2
290 Broadway - 16th Floor
New York, New York 10007

75. If Respondent fails to make full and complete payment of the $66,770 penalty that is required by this CAFO, this case may be referred by EPA to the United States Department of Justice and/or the United States Department of the Treasury for collection. In such an action, pursuant to Section 113(d)(5) of the CAA, 42 U.S.C. § 7413(d)(5) and 31 U.S.C. § 3717, Respondent shall pay the following amounts:

i. Interest. If Respondent fails to make payment, or makes partial payment, any unpaid portion of the assessed penalty shall bear interest at the rate established pursuant to 31 U.S.C. § 3717 and 26 U.S.C. § 6621 from the payment Due Date.

ii. Handling Charges. Pursuant to 31 U.S.C. § 3717(e)(1), a monthly handling Charge of fifteen dollars ($15.00) shall be paid if any portion of the assessed penalty is more than thirty (30) days past the payment Due Date.

iii. Attorney Fees, Collection Costs, Nonpayment of Penalty. If Respondent fails to pay the amount of an assessed penalty on time, pursuant to 42 U.S.C. § 7413(d)(5), in addition to such assessed penalty and interest and handling assessrnents, Respondent shall also pay the United States' enforcement expenses, including but not limited to attorney fees and costs incurred by the United States for collection proceedings, and a quarterly nonpayment penalty for each quarter during which such failure to pay persists. Such nonpayment penalty shall be ten percent of the aggregate amount of Respondent's outstanding penalties and nonpayment penalties accrued from the beginning of such quarter.

76. This Consent Agreement is being entered into voluntarily and knowingly in full settlement of Respondent's alleged violations of the Act set forth herein.

77. Respondent has read the Consent Agreement, finds it reasonable and consents to terms and issuance as a Final Order.

78. Nothing in this CAFO shall relieve Respondent of the duty to comply with all applicable provisions of the CAA and other environmental laws, nor shall this CAFO affect the right of the United States to pursue appropriate injunctive or other equitable relief or criminal sanctions for any violations of law.

79. Respondent explicitly waives its right to request a hearing and/or contest allegations in this Consent Agreement or the attached Final Order and explicitly waives its right to appeal the attached Final Order.

80. Respondent waives any right it may have pursuant to 40 C.F.R. § 22.08 to be present during discussions with, or to be served with and to reply to any memorandum or communication addressed to, the Regional Administrator or the Deputy Regional Administrator where the purpose of such discussion, memorandum, or communication is to recommend that such official accept this Consent Agreement and issue the attached Final Order.

81. Each party to this CAFO shall bear its own costs and attorney fees in the action resolved by this Consent Agreement.

82. This CAFO shall be binding on Respondent and its successors and assignees.

83. Each of the undersigned representative(s) to this CAFO certifies that he or she is duly authorized by the party whom he or she represents to enter into the terms and conditions of this CAFO and bind that party to it.

For Respondent:

Roberta L. McKee

Roberta McKee
Senior Vice President
North America Drug
Product Operations
Bristol-Myers Squibb Co.

Date September 15, 2008

For Complainant:

PATRICK DURACK
FOR

Dore LaPosta, Director
Division of Enforcement &
Compliance Assistance
United States Environmental
Protection Agency, Region 2

Date SEPTEMBER 23, 2008

FINAL ORDER

The Regional Administrator of EPA, Region 2, concurs in the foregoing Consent Agreement resolving the CAA matter: Bristol-Myers Squibb Company and Humacao, Puerto Rico Facility and Barceloneta, Puerto Rico Facility CAA-02-2008-1212. The Consent Agreement in this matter is hereby approved and issued, as a Final Order, effective immediately.

DATE: 9-29-08

Alan J. Steinberg
Regional Administrator
U.S. Environmental Protection
Agency - Region 2