

benefits of prompt and less costly settlement through the consent decree process.” 119 Cong. Rec. 24,598 (1973) (statement of Senator Tunney).<sup>1</sup> Rather:

[a]bsent a showing of corrupt failure of the government to discharge its duty, the Court, in making its public interest finding, should \* \* \* carefully consider the explanations of the government in the competitive impact statement and its responses to comments in order to determine whether those explanations are reasonable under the circumstances.

*United States v. Mid-America Dairymen, Inc.*, 1977–1 Trade Cas. (CCH) ¶ 61,508, at 71,980 (W.D. Mo. 1977).

Accordingly, with respect to the adequacy of the relief secured by the decree, a court may not “engage in an unrestricted evaluation of what relief would best serve the public.” *United States v. BNS, Inc.*, 858 F.2d 456, 462 (9th Cir. 1988) (citing *United States v. Bechtel Corp.*, 648 F.2d 660, 666 (9th Cir. 1981)); see also *Microsoft*, 56 F.3d at 1460–62. Courts have held that:

[t]he balancing of competing social and political interests affected by a proposed antitrust consent decree must be left, in the first instance, to the discretion of the Attorney General. The court’s role in protecting the public interest is one of insuring that the government has not breached its duty to the public in consenting to the decree. The court is required to determine not whether a particular decree is the one that will best serve society, but whether the settlement is “within the reaches of the public interest.” More elaborate requirements might undermine the effectiveness of antitrust enforcement by consent decree.

*Bechtel*, 648 F.2d at 666 (emphasis added) (citations omitted).<sup>2</sup>

The proposed Final Judgment, therefore, should not be reviewed under

a standard of whether it is certain to eliminate every anticompetitive effect of a particular practice or whether it mandates certainty of free competition in the future. Court approval of a final judgment requires a standard more flexible and less strict than the standard required for a finding of liability. “[A] proposed decree must be approved even if it falls short of the remedy the court would impose on its own, as long as it falls within the range of acceptability or is ‘within the reaches of public interest.’” *United States v. AT&T*, 552 F. Supp. 131, (D.D.C. 1982) (citations omitted) (quoting *Gillette*, 406 F. Supp. at 716), aff’d sub nom. *Maryland v. United States*, 460 U.S. 1001 (1983); see also *United States v. Alcan Aluminum Ltd.*, 605 F. Supp. 619, 622 (W.D. Ky. 1985) (approving the consent decree even though the court would have imposed a greater remedy).

Moreover, the Court’s role under the APPA is limited to reviewing the remedy in relationship to the violations that the United States has alleged in its Complaint; the APPA does not authorize the Court to “construct [its] own hypothetical case and then evaluate the decree against that case.” *Microsoft*, 56 F.3d at 1459. Because the “court’s authority to review the decree depends entirely on the government’s exercising its prosecutorial discretion by bringing a case in the first place,” it follows that “the court is only authorized to review the decree itself,” and not to “effectively redraft the complaint” to inquire into other matters that the United States did not pursue. *Id.* at 1459–60.

## VIII. Determinative Documents

There are no determinative materials or documents within the meaning of the APPA that were considered by the United States in formulating the proposed Final Judgment.

Dated: March 21, 2005.

Respectfully submitted,

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### Importation of Controlled Substances; Notice of Application

Pursuant to 21 U.S.C. 958(1), the Attorney General shall, prior to issuing a registration under this Section to a bulk manufacturer of a controlled substance in Schedule I or II and prior to issuing a regulation under 21 U.S.C. 952(a)(2)(b) authorizing the importation of such substances, provide manufacturers holding registrations for the bulk manufacture of the substances an opportunity for a hearing.

Therefore, in accordance with Title 21 CFR 1301.34(a), this is notice that on July 26, 2004, Aveva Drug Delivery Systems Inc., 3250 Commerce Parkway, Miramar, Florida 33025–3907, made application to the Drug Enforcement Administration (DEA) for registration as an importer of Fentanyl (9801), a basic class of controlled substance listed in Schedule II.

The company plans to import the listed controlled substance for the manufacture of analytical reference standards.

Any manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic classes of controlled substances may file written comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43 and in such form as prescribed by 21 CFR 1316.47.

Any such written comments or objections being sent via regular mail may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative, Liaison and Policy Section (ODL); or any being sent via express mail should be sent to DEA Headquarters, Attention: DEA Federal Register Representative/ODL, 2401 Jefferson Davis Highway, Alexandria, Virginia 22301; and must be filed no later than May 4, 2004.

This procedure is to be conducted simultaneously with and independent of the procedures described in 21 CFR 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice published in the **Federal Register** on September 23, 1975, (40 FR 43745–46), all applicants for registration to import the basic class of any controlled substance listed in Schedule I or II are and will continue to be required to demonstrate to the Deputy Assistant Administrator, Office

<sup>1</sup> See *United States v. Gillette Co.*, 406 F. Supp. 713, 716 (D. Mass. 1975) (recognizing it was not the court’s duty to settle; rather, the court must only answer “whether the settlement achieved [was] within the reaches of the public interest”). A “public interest” determination can be made properly on the basis of the Competitive Impact Statement and Response to Comments filed by the Department of Justice pursuant to the APPA. Although the APPA authorizes the use of additional procedures, 15 U.S.C. 16(f), those procedures are discretionary. A court need not invoke any of them unless it believes that the comments have raised significant issues and that further proceedings would aid the court in resolving those issues. See H.R. Rep. No. 93–1463, 93rd Cong 2d Sess. 8–9 (1974), reprinted in 1974 U.S.C.C.A.N. 6535, 6538.

<sup>2</sup> Cf. *BNS*, 858 F.2d at 464 (holding that the court’s “ultimate authority under the [APPA] is limited to approving or disapproving the consent decree”); *Gillette*, 406 F. Supp. at 716 (noting that, in this way, the court is constrained to “look at the overall picture not hypercritically, nor with a microscope, but with an artist’s reducing glass”). See generally *Microsoft*, 56 F.3d at 1461 (discussing whether “the remedies [obtained in the decree are] so inconsonant with the allegations charged as to fall outside of the ‘reaches of the public interest’”).

of Diversion Control, Drug Enforcement Administration that the requirements for such registration pursuant to 21 U.S.C. 958(a), 21 U.S.C. 823(a), and 21 CFR 1301.34(b), (c), (d), (e), and (f) are satisfied.

Dated: March 25, 2005.

**William J. Walker,**

*Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.*

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### Manufacturer of Controlled Substances; Notice of Registration

By Notice dated December 21, 2004, and published in the **Federal Register** on January 4, 2005, (70 FR 390), Cedarburg Pharmaceuticals, Inc., 870 Badger Circle, Grafton, Wisconsin 53024, made application by letter to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the basic classes of controlled substances listed in Schedule II:

Drug	Schedule
Dihydrocodeine (9120) .....	II
Remifentanyl (9739) .....	II
Sufentanil (9740) .....	II

The company plans to manufacture the listed controlled substances in bulk for distribution to its customers.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Cedarburg Pharmaceuticals, Inc. to manufacture the listed basic classes of controlled substances is consistent with the public interest at this time. DEA has investigated Cedarburg Pharmaceuticals, Inc. to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823, and in accordance with 21 CFR 1301.33(a), the above named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed.

Dated: March 25, 2005.

**William J. Walker,**

*Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.*

[FR Doc. 05-6592 Filed 4-1-05; 8:45 am]

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### Manufacturer of Controlled Substances; Notice of Application

Pursuant to 21 CFR 1301.33(a), Title 21 of the Code of Federal Regulations (CFR), this is notice that on February 7, 2005, Johnson Matthey, Inc., Custom Pharmaceuticals Department, 2003 Nolte Drive, West Deptford, New Jersey 08066, made application by letter to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of Methamphetamine (1105), a basic class of controlled substance listed in Schedule II.

The company plans to manufacture the listed controlled substance in bulk for distribution to its customers.

Any other such applicant and any person who is presently registered with DEA to manufacture such a substance may file comments or objections to the issuance of the proposed registration pursuant to 21 CFR 1301.33(a).

Any such written comments or objections being sent via regular mail may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative, Liaison and Policy Section (ODL); or any being sent via express mail should be sent to DEA Headquarters, Attention: DEA Federal Register Representative/ODL, 2401 Jefferson Davis Highway, Alexandria, Virginia 22301; and must be filed no later than June 3, 2005.

Dated: March 25, 2005.

**William J. Walker,**

*Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.*

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### Manufacturer of Controlled Substances; Notice of Application

Pursuant to section 1301.33(a) of Title 21 of the Code of Federal Regulations

(CFR), this is notice that on January 4, 2005, Mallinckrodt Inc., Mallinckrodt & Second Streets, St. Louis, Missouri 63147, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the basic classes of controlled substances listed in Schedules I and II:

Drug	Schedule
Tetrahydrocannabinols (7370) .....	I
Codeine-N-oxide (9053) .....	I
Dihydromorphine (9145) .....	I
Difenoxin (9168) .....	I
Heroin (9200) .....	I
Morphine-N-oxide (9307) .....	I
Nicomorphine (9312) .....	I
Normorphine (9313) .....	I
Norlevorphanol (9634) .....	I
Amphetamine (1100) .....	II
Methamphetamine (1105) .....	II
Methylophenidate (1724) .....	II
Codeine (9050) .....	II
Diprenorphine (9058) .....	II
Etorphine HCL (9059) .....	II
Dihydrocodeine (9120) .....	II
Hydromorphone (9150) .....	II
Oxycodone (9143) .....	II
Diphenoxylate (9170) .....	II
Benzoylcegonine (9180) .....	II
Hydrocodone (9193) .....	II
Levorphanol (9220) .....	II
Meperidine (9230) .....	II
Methadone (9250) .....	II
Methadone Intermediate (9254) ..	II
Metopon (9260) .....	II
Dextropropoxyphene (9273) .....	II
Morphine (9300) .....	II
Thebaine (9333) .....	II
Opium extracts (9610) .....	II
Opium fluid extract (9620) .....	II
Opium tincture (9630) .....	II
Opium, powdered (9639) .....	II
Opium, granulated (9640) .....	II
Levo-alphaacetylmethadol (9648) ..	II
Oxymorphone (9652) .....	II
Alfentanil (9737) .....	II
Remifentanyl (9739) .....	II
Sufentanil (9740) .....	II
Fentanyl (9801) .....	II

The company plans to manufacture the listed controlled substances for internal use and for distribution to its customers.

Any other such applicant and any person who is presently registered with DEA to manufacture such a substance may file comments or objections to the issuance of the proposed registration pursuant to 21 CFR 1301.33(a).

Any such written comments or objections being sent via regular mail may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative, Liaison and Policy Section (ODL); or any being sent via express mail should be sent to