On February 15, 1991, in accordance with 21 U.S.C. 811(b), the Administrator of the DEA requested that the Assistant Secretary for Health conduct a scientific and medical evaluation of the thebaine-derived butorphanol and provide the DEA with a recommendation concerning the scheduling of this drug. On October 28, 1991, following a review of relevant medical and scientific data, the Assistant Secretary for Health recommended that thebaine-derived butorphanol be decontrolled from Schedule II.

Accordingly, on April 3, 1992, the Administrator published a notice in the Federal Register proposing to remove thebaine-derived butorphanol from Schedule II of the CSA. The notice provided a 60-day period during which comments and objections to the proposed rulemaking could be sent to the Administrator. As of June 3, 1992 the Administrator did not receive any comments or objections regarding the proposal to remove thebaine-derived butorphanol from Schedule II of the CSA.

The Administrator of the DEA hereby certifies that this final rule will have no significant impact upon entities whose interests must be considered under the Regulatory Flexibility Act 5 U.S.C. 601 et seq. This scheduling matter is a formal action required by statute to be made on the record after opportunity for an agency hearing. It is not a major rule for purposes of Executive Order (E.O.) 12291. Accordingly, it has not been submitted for review by the Office of Management and Budget (OMB) pursuant to the provisions of Executive Order 12291. This matter is not subject to those provisions of Executive Order 12778, which are contingent upon review by OMB. As a formal rulemaking, this action is not subject to the moratorium on regulations ordered by the President in his memorandum of January 28, 1992.

This action has been analyzed in accordance with the principles and criteria in Executive Order 12861, and it has been determined that this matter does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Preparation drugs.

Under the authority vested in the Attorney General by section 201(a) of the CSA (21 U.S.C. 811(a)) and delegated to the Administrator of the DEA by Department of Justice Regulations (28 CFR 0.100), the Administrator hereby orders that 21 CFR part 1308 be amended as follows:

PART 1308—[AMENDED]

1. The authority citation for 21 CFR part 1308 continues to read as follows:
   Authority: 21 U.S.C. 811, 812, 871(b)

2. Section 1308.12(b)(1) introductory text is revised to read as follows:

§ 1308.12 Schedule II.

   (b) * * *

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate excluding apomorphine, thebaine-derived butorphanol, dextrophan, nalbuphine, nalorphine, naloxone, and naltrexone, and their respective salts, but including the following:

   * * *

Dated: July 6, 1992.

Robert C. Bonner,
Administrator, Drug Enforcement Administration.

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