

conservative assumptions (erring on the side of inclusiveness), DEA estimated that the total sales of edible “hemp” products in the United States is no more than \$20 million per year with no more than 500 persons employed in connection with these products. In the publication of the proposed rule, DEA urged any manufacturer or distributor of “hemp” products to submit during the comment period any data on this economic activity that might warrant adjustments to these estimates. The comments that DEA received suggest that the agency might have overestimated the amount of economic activity tied to edible “hemp” products. The highest estimate submitted by representatives of businesses that produce and distribute edible “hemp” products was that the total sales of such products in the United States is approximately \$6 million.

It also must be noted that not every such edible product marketed as a “hemp” product is necessarily prohibited under the rule being finalized today. As DEA stated repeatedly in the text accompanying the proposed rule and the interim rule, if a product says “hemp” on the label but contains no THC (or any other controlled substance), it is not a controlled substance and, therefore, not affected by this rule. At least one “hemp” food company claims that its products are THC-free.<sup>17</sup> If this is correct, such products are not controlled substances and not prohibited by the CSA. Thus, even if the edible “hemp” products business is a \$6 million industry in the United States, some of that business might be able to continue under this final rule.

The one other category of products that might be impacted economically by this rule is that in which pure cannabis seeds are sold as birdseed. (As set forth in the interim rule, which is being finalized today, DEA is exempting animal feed mixtures containing sterilized cannabis seeds with other ingredients, but not pure sterilized cannabis seeds.) In the regulatory certifications attached to the proposed rule, DEA estimated that no more than

\$77,000 worth of birdseed that contains cannabis seeds is imported into the United States for sale in this country. It appears likely that most of this birdseed is sold in a mixture that is exempted under the interim rule. Accordingly, the total amount of pure “hempseeds” sold as birdseed in this country is probably much less than \$77,000.

#### *Regulatory Flexibility Act*

For the reasons provided above, the Acting Administrator hereby certifies that this rule will not have a significant impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act (5 U.S.C. 605(b)). The economic activity that would be disallowed under this rule is already illegal under DEA’s interpretation of existing law. Even if one were to assume that such economic activity were legal under current law, the prohibition on such activity resulting from this rule (summarized above) would not constitute significant impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act. Therefore, a final regulatory flexibility analysis is not required for this rule.

#### *Executive Order 12866*

This rule has been drafted and reviewed in accordance with Executive Order 12866, Regulatory Planning and Review, 1(b), Principles of Regulation. This rule has been determined to be a “significant regulatory action” under Executive Order 12866, 3(f). Accordingly, this rule has been reviewed by the Office of Management and Budget for purposes of Executive Order 12866.

#### *Executive Order 13132*

This rule does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this rule does not have federalism implications warranting the application of Executive Order 13132.

#### *Executive Order 12988—Civil Justice Reform*

This rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

#### *Unfunded Mandates Reform Act of 1995*

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more in any one year. Therefore, no actions

are necessary under the Unfunded Mandates Reform Act of 1995.

#### *Small Business Regulatory Enforcement Fairness Act of 1996*

For the reasons provided above, this rule is not likely to result in any of the following: An annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices for consumers, individual industries, federal, state, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. The economic activity disallowed under this rule is already illegal under DEA’s interpretation of existing law. Even if one were to assume that such economic activity were legal under current law, the prohibition on such activity resulting from this rule would not render the rule a major rule under the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 804. Therefore, the provisions of SBREFA relating to major rules are inapplicable to this rule. However, a copy of this rule has been sent to the Office of Advocacy, Small Business Administration. Further, a copy of this final rule will be submitted to each House of the Congress and to the Comptroller General in accordance with SBREFA (5 U.S.C. 801).

#### *Paperwork Reduction Act of 1995*

This rule does not involve collection of information within the meaning of the Paperwork Reduction Act of 1995.

#### **List of Subjects in 21 CFR Part 1308**

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

#### **Final Rule**

Pursuant to the authority vested in the Attorney General under sections 201, 202, and 501(b) of the CSA (21 U.S.C. 811, 812, and 871(b)), delegated to the Administrator and Deputy Administrator pursuant to section 501(a) (21 U.S.C. 871(a)) and as specified in 28 CFR 0.100 and 0.104, appendix to subpart R, sec. 12, the Acting Administrator hereby orders that Title 21 of the Code of Federal Regulations, part 1308, be amended as follows:

#### **PART 1308—[AMENDED]**

1. The authority citation for part 1308 continues to read as follows:

<sup>17</sup> On January 28, 2002, a company that sells “hemp” food products issued the following statement on its website (<http://www.thehempnut.com>): It is the position of HempNut, Inc. and the Hemp Food Association (HFA) that this Rule [published by DEA on October 9, 2001] is merely a clarification and confirmation of the basis under which DEA, US Customs, and all responsible hempseed importers have already been operating under for quite some time, namely, that hempseed products may not contain tetrahydrocannabinol (THC). A survey of hempseed importers revealed that all were in full compliance with the Rule, and have no THC in their products.