

Avenue, Rensselaer, New York 12144, made application by renewal to the Drug Enforcement Administration (DEA) as a bulk manufacturer of the basic classes of controlled substances listed in schedules I and II:

Drug	Schedule
Marihuana (7360)	I
Tetrahydrocannabinols (7370)	I
Amphetamine (1100)	II
Lisdexamfetamine (1205)	II
Methylphenidate (1724)	II
Pentobarbital (2270)	II
Hydrocodone (9193)	II
Meperidine (9230)	II
Dextropropoxyphene, bulk (non-dosage form) (9273)	II
Oxymorphone (9652)	II
Fentanyl (9801)	II

The company plans to manufacture bulk controlled substances for use in product development and for distribution to its customers.

In reference to drug code 7360 (Marihuana), the company plans to bulk manufacture cannabidiol as a synthetic intermediate. This controlled substance will be further synthesized to bulk manufacture a synthetic THC (7370). No other activity for this drug code is authorized for this registration.

Any other such applicant, and any person who is presently registered with DEA to manufacture such substances, 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 should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrisette Drive, Springfield, Virginia 22152; and must be filed no later than June 29, 2009.

Dated: April 17, 2009.

Joseph T. Rannazzisi,

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

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be registered as a bulk manufacturer of Methamphetamine (1105), a basic class of controlled substance listed in schedule II.

The company plans to manufacture bulk controlled substances for use in product development 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 should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrisette Drive, Springfield, Virginia 22152; and must be filed no later than June 29, 2009.

Dated: April 17, 2009.

Joseph T. Rannazzisi,

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 § 1301.33(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on February 20, 2009, Stepan Company, Natural Products Dept., 100 W. Hunter Avenue, Maywood, New Jersey 07607, made application by renewal to the Drug Enforcement Administration (DEA) as a bulk manufacturer of the basic classes of controlled substances listed in schedule II:

Drug	Schedule
Cocaine (9041)	II
Benzoylcegonine (9180)	II

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

Any other such applicant, and any person who is presently registered with DEA to manufacture such substances, 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 should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative

(ODL), 8701 Morrisette Drive, Springfield, Virginia 22152; and must be filed no later than June 29, 2009.

Dated: April 17, 2009.

Joseph T. Rannazzisi,

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

[FR Doc. E9-9807 Filed 4-28-09; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Bob's Pharmacy and Diabetic Supplies; Revocation of Registration

On August 15, 2008, I, the Deputy Administrator of the Drug Enforcement Administration, issued an Order to Show Cause and Immediate Suspension of Registration to Bob's Pharmacy and Diabetic Supplies (Respondent), of Winter Haven, Florida. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration, FB0181216, as a retail pharmacy, and the denial of any pending application to renew or modify its registration, on the ground that Respondent has committed acts which render its "continued registration inconsistent with the public interest." Show Cause Order at 1 (citing 21 U.S.C. 824(a)(4)).

The Show Cause Order alleged that Respondent was "knowingly engaging in a scheme to distribute controlled substances based on * * * prescriptions that [were] issued for other than legitimate medical purpose and by physicians acting outside [of] the usual course of professional practice, in violation of * * * Federal and State law." *Id.* (citing 21 CFR 1306.04; *United Prescriptions Servs., Inc.*, 72 FR 50397 (2007)). More specifically, the Show Cause Order alleged that Respondent was "dispensing controlled substances into states in which it is not licensed to do so," and that it was "aiding physicians in the unauthorized practice of medicine in those states that require physicians to be licensed by the state before prescribing controlled substances to state residents." *Id.* at 2 (citing *United*, 72 FR 50407-08). The Show Cause Order also alleged that Respondent had "dispensed large quantities of controlled substances based on prescriptions purportedly written by Sheila Soman, M.D., a physician who was not authorized by DEA to prescribe controlled substances." *Id.* Based on the above, I further found that there was a "substantial likelihood that [Respondent

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to § 1301.33(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on May 22, 2008, Norac Inc., 405 S. Motor Avenue, P.O. Box 577, Azusa, California 91702-3232, made application by letter to the Drug Enforcement Administration (DEA) to

would] continue to divert large quantities of controlled substances,” and concluded that Respondent’s continued registration during the pendency of the proceeding “would constitute an imminent danger to the public health and safety.” *Id.* I therefore ordered that Respondent’s registration be immediately suspended.¹ *Id.*

On August 20, 2008, a DEA Investigator personally served the Order on Respondent. Since that time neither Respondent, nor anyone purporting to represent it, has requested a hearing. Because more than thirty days have elapsed since Respondent was served with the Order, and Respondent has not requested a hearing, I conclude that Respondent has waived its right to a hearing. 21 CFR 1301.43(d). I therefore enter this Decision and Final Order based on relevant material contained in the investigative file and make the following findings. *Id.* 1301.43(e).

Findings

Respondent is the holder of DEA Certificate of Registration, FB0181216, which authorizes it to dispense, as a retail pharmacy, controlled substances in schedules II through V, at the registered location of 2860 Highway 17 N., Winter Haven, Florida 33881. Respondent was first registered with the Agency on or about March 14, 2007; its registration does not expire until July 31, 2009. Respondent is owned by Mr. Robert L. Grable.

In August 2007, a DEA Investigator (DI) obtained a report which indicated that between April 15 and June 28, 2007, Respondent had purchased 767,900 dosage units of drugs containing hydrocodone, a controlled substance highly popular with drug abusers. Moreover, between June 28 and September 12, 2007, Respondent ordered a further 258,000 dosage units of hydrocodone from just one of its suppliers. Subsequent reports further showed that between April 25 and December 28, 2007, Respondent had purchased 2.3 million dosage units of drugs containing hydrocodone, or approximately 287,000 dosage units per month. By way of contrast, I have previously found that the national average purchase of combination hydrocodone drugs by retail pharmacies is approximately 6,000 dosage units. See *Southwood Pharmaceuticals, Inc.*, 71 FR 36487, 36490 (2007).

On January 10, 2008, the DEA Nashville Diversion Group received a letter from the compliance officer for Top Rx, Inc., a registered distributor. The letter indicated that Respondent had applied to become a customer of Top Rx and had completed a questionnaire on which it indicated that it did not dispense controlled substances through the internet. Top Rx’s compliance office determined, however, that Respondent may have been affiliated with a Web site which provided illegal prescriptions for controlled substances.

Approximately a week later, the DI received information from the New York Diversion Group that Respondent had ordered 700 grams of pure hydrocodone powder (a schedule II controlled substance) from another distributor. Finally, in a December 27, 2007 letter, a third distributor identified Respondent as having placed excessive orders.

On June 27, 2008, two DIs visited Respondent. During the visit, the DIs obtained prescriptions which had been issued by two physicians (one based in Tampa, Florida; the other based in Deridder, Louisiana) which had been issued to persons throughout the United States, and which were dispensed by Respondent. Ninety-seven percent of the prescriptions were for schedule III controlled substances containing hydrocodone and were typically for ninety tablets; some of the remaining prescriptions were for alprazolam, a schedule IV controlled substance.

On August 20, 2008, an Administrative Inspection Warrant was served on Respondent. Pursuant to the search, the DIs obtained numerous prescription records. According to the sworn declaration of a DI who reviewed the records, between May 3, 2007, and the date that the warrant was executed, Respondent had filled in excess of 38,000 prescriptions for controlled substances, the great majority of which were for schedule III drugs containing hydrocodone.

The DI found that Respondent had filled more than 6,000 prescriptions issued by Dr. Celeste Lujan, who was authorized to practice medicine and prescribe controlled substances only in Louisiana and Texas. According to the DI, most of the prescriptions were issued to persons who resided in States where Dr. Lujan was not authorized to practice medicine including Alaska, Alabama, Arkansas, Arizona, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Iowa, Idaho, Illinois, Indiana, Kansas, Massachusetts, Maryland, Maine, Michigan, Minnesota, Missouri, Mississippi, Montana, New

Hampshire, New Jersey, New Mexico, New York, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Utah, Virginia, Washington, Wisconsin, West Virginia, and Wyoming.

The DI further found that between January 1 and August 18, 2008, Respondent filled more than 3,000 prescriptions which were written under the DEA registration issued to Dr. Sheila Soman of New York, NY. Dr. Soman had, however, previously voluntarily surrendered her registration; on December 17, 2007, the Agency retired her registration.

Discussion

Section 304(a) of the Controlled Substance Act provides that “[a] registration * * * to * * * dispense a controlled substance * * * may be suspended or revoked by the Attorney General upon a finding that the registrant * * * has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section.” 21 U.S.C. 824(a). In determining the public interest, the Act directs that the Attorney General consider the following factors:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant’s experience in dispensing * * * controlled substances.

(3) The applicant’s conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

Id. § 823(f).

“[T]hese factors are * * * considered in the disjunctive.” *Robert A. Leslie, M.D.*, 68 FR 15227, 15230 (2003). I “may rely on any one or a combination of factors, and may give each factor the weight [I] deem[] appropriate in determining whether a registration should be revoked.” *Id.* Moreover, case law establishes that I am “not required to make findings as to all of the factors.” *Hoxie v. DEA*, 419 F.3d 477, 482 (6th Cir. 2005); see also *Morall v. DEA*, 412 F.3d 165, 173–74 (D.C. Cir. 2005). Finally, where the Government has made out its *prima facie* case, the burden shifts to the Respondent to show why its continued registration would be consistent with the public interest. See, e.g., *Theodore Neujahr*, 65 FR 5680, 5682 (2000); *Service Pharmacy, Inc.*, 61 FR 10791, 10795 (1996).

¹ The Show Cause Order also informed Respondent of its right to request a hearing on the allegations; the date, time, and place of the hearings; its right to submit a written statement in lieu of a hearing; and the consequences if it failed to request a hearing. Show Cause Order at 2.

In this case, having considered all of the factors, I conclude that the Government's evidence with respect to factors two and four establishes a *prima facie* case that Respondent's continued registration is "inconsistent with the public interest." 21 U.S.C. 823(f). Accordingly, Respondent's registration will be revoked and any pending applications for renewal of its registration will be denied.

Factor Two—Respondent's Experience in Dispensing Controlled Substances

Under DEA's regulation, a prescription for a controlled substance is unlawful unless it has been "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 CFR 1306.04(a). The regulation further provides that while "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, * * * a corresponding responsibility rests with the pharmacist who fills the prescription." *Id.* (emphasis added). Continuing, the regulation states that "the person knowingly filling such a purported prescription, as well as the person issuing it, [is] subject to the penalties provided for violations of the provisions of law relating to controlled substances." *Id.*

DEA has long interpreted this provision "as prohibiting a pharmacist from filling a prescription for a controlled substance when he either 'knows or has reason to know that the prescription was not written for a legitimate medical purpose.'" *Medicine Shoppe-Jonesborough*, 73 FR 363, 381 (2008) (quoting *Medic-Aid Pharmacy*, 55 FR 30043, 30044 (1990)), *aff'd Medicine Shoppe-Jonesborough v. DEA*, 2008 WL 4899525 (6th Cir. 2008); see also *Frank's Corner Pharmacy*, 60 FR 17574, 17576 (1995); *Ralph J. Bertolino*, 55 FR 4729, 4730 (1990); *United States v. Seelig*, 622 F.2d 207, 213 (6th Cir. 1980). This Agency has further held that "[w]hen prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes and thereby avoid [actual] knowledge of the real purpose of the prescription." *Bertolino*, 55 FR at 4730 (citations omitted).²

² The Supreme Court has recently explained that "the prescription requirement * * * ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the drugs for those prohibited uses." *Gonzales v. Oregon*, 546 U.S. 243, 274 (2006) (citing *United States v. Moore*, 423 U.S. 122, 135 (1975)).

In *United Prescription Services, Inc.*, I further held that "[a] physician who engages in the unauthorized practice of medicine is not a 'practitioner acting in the usual course of * * * professional practice.'" 21 CFR 1306.04(a). This rule derives from the text of the CSA, which defines "[t]he term 'practitioner' [to] mean[] a physician * * * licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices * * * to * * * dispense * * * a controlled substance." 21 U.S.C. 802(21). See also 21 U.S.C. 823(f) ("The Attorney General shall register practitioners * * * to dispense * * * if the applicant is authorized to dispense * * * controlled substances under the laws of the State in which he practices."). As the Supreme Court has explained: "In the case of a physician [the CSA] contemplates that *he is authorized by the State to practice medicine* and to dispense drugs in connection with his professional practice." *United States v. Moore*, 423 U.S. 122, 140–41 (1975) (emphasis added). A controlled-substance prescription issued by a physician who lacks the license necessary to practice medicine within a State is therefore unlawful under the CSA. *Cf.* 21 CFR 1306.03(a)(1) ("A prescription for a controlled substance may be issued only by an individual practitioner who is * * * [a]uthorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession[.]").

Respondent had ample reason to know that the prescriptions issued by Dr. Lujan were unlawful under both Federal and state law. As the California Court of Appeal has noted: The "proscription of the unlicensed practice of medicine is neither an obscure nor an unusual state prohibition of which ignorance can reasonably be claimed, and certainly not by persons * * * who are licensed health care providers. Nor can such persons reasonably claim ignorance of the fact that authorization of a prescription pharmaceutical constitutes the practice of medicine." *Hageseth v. Superior Court*, 59 Cal. Rptr. 3d 385, 403 (Ct. App. 2007);³ see

³ In *Hageseth*, the California Court of Appeal upheld the State's jurisdiction to criminally prosecute an out-of-state physician, who prescribed a drug to a California resident over the internet, for the unauthorized practice of medicine.

Moreover, the Medical Board of California has issued numerous Citation Orders to out-of-state physicians for internet prescribing to state residents. See, e.g., *Citation Order Harry Hoff* (June 17, 2003); *Citation Order Carlos Gustavo Levy* (Nov. 30, 2001). It has also issued press releases announcing its position on the issuance of prescriptions by physicians who do not hold a California license. See Medical Board of California,

Cal. Bus. & Prof. Code § 2052 (prohibiting unlicensed practice of medicine); Cal. Health & Safety Code § 11352(a) (prohibiting furnishing a controlled substance "unless upon the written prescription of a physician * * * licensed to practice in this state"). See also e.g., Ala. Code § 34–24–501(a) (defining practice of medicine across state lines); *id.* § 34–24–502(a) (requiring special purpose license to practice medicine across state lines); Ga. Code Ann. § 43–34.31.1(a) (defining practice of medicine to include electronic prescribing by "[a] person who is physically located in another state" and requiring Georgia license); 225 Ill. Comp. Stat. Ann. § 60/3 (licensure requirement); *id.* § 60/3.5 (prohibiting unlicensed practice); *id.* § 60/49 (listing acts constituting holding oneself out to the public as a physician); *id.* § 60/49.5 (requiring persons engaged in telemedicine to hold Illinois license); N.H. Rev. Stat. § 329:1 (defining practice of medicine); *id.* § 329:24 (unlicensed practice).

As I have previously explained, an entity which voluntarily engages in commerce by shipping controlled substances to persons located in other States is properly charged with knowledge of the laws regarding both the practice of medicine and pharmacy in those States. *United*, 72 FR at 50408. In short, given that Dr. Lujan was licensed to practice medicine and prescribe in only Louisiana and Texas, and yet was prescribing to persons who did not reside in those States and lived hundreds of—and in many instances more than a thousand—miles away, Respondent had ample reason to know that the prescriptions were unlawful under both the CSA and the laws of numerous States. See *id.* at 50409.

Moreover, under DEA regulations, a prescription for a controlled substance can be issued only by a practitioner who holds a registration with the Agency. 21 CFR 1306.03(a) ("A prescription for a controlled substance may be issued only by an individual practitioner who is * * * registered.").⁴ Respondent thus also violated the CSA when it filled more than 3,000 prescriptions which were purportedly issued by Dr. Soman, a physician who had previously voluntarily surrendered her registration.

Record Fines Issued by Medical Board to Physicians in Internet Prescribing Cases (News Release, Feb. 10, 2003) (available at http://www.mbc.ca.gov/NR_2003_02-10_Internetdrugs.htm).

⁴ It is unclear whether the prescriptions issued under Dr. Soman's expired registration were actually issued by her. What is clear is that no prescription could be lawfully issued (or filled) under her registration number.

As the foregoing demonstrates, Respondent's experience in dispensing controlled substances is characterized by its repeated and flagrant violations of the CSA and state laws. Indeed, within less than one month of obtaining its registration, Respondent proceeded to purchase hundreds of thousands of dosage units of hydrocodone, quantities which exceeded by nearly fifty times the average purchase of this drug by legitimate pharmacies. As this evidence shows, Respondent was engaged in a criminal scheme to divert controlled substances.

I therefore hold that Respondent's continued registration is "inconsistent with the public interest" and that its registration should be revoked. 21 U.S.C. 823(f). For the same reasons that I ordered the immediate suspension of Respondent's registration, I further hold that this Order shall be effective immediately.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) & 824(a), as well as 28 CFR 0.100(b) & 0.104, I hereby order that DEA Certificate of Registration, FB0181216, issued to Bob's Pharmacy and Diabetic Supplies be, and it hereby is, revoked. I further order that any pending applications for renewal or modification of such registration be, and they hereby are, denied. This Order is effective immediately.

Dated: April 3, 2009.

Michele M. Leonhart,
Deputy Administrator.

[FR Doc. E9-9797 Filed 4-28-09; 8:45 am]

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DEPARTMENT OF LABOR

Employment and Training Administration Submission for OMB Emergency Review: Revision of OMB Control No. 1205-0342, Petition and Investigative Forms To Assess Group Eligibility for Trade Adjustment Assistance, Comment Request

April 24, 2009.

The Department of Labor (DOL) has submitted the following information collection request (ICR), utilizing the Paperwork Reduction Act (PRA) emergency review procedures, to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. Chapter 35) and 5 CFR 1320.13. OMB approval is requested by May 6, 2009. A copy of this ICR, with applicable supporting documentation;

including among other things a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained from the RegInfo.gov Web site at <http://www.reginfo.gov/public/do/PRAMain> or by contacting Darrin King on 202-693-4129 (this is not a toll-free number)/e-mail:

DOL_PRA_PUBLIC@dol.gov. Interested parties are encouraged to send comments to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Department of Labor—ETA, Office of Management and Budget, Room 10235, Washington, DC 20503, Telephone: 202-395-7316/Fax: 202-395-6974 (these are not toll-free numbers), E-mail:

OIRA_submission@omb.eop.gov. Comments and questions about the ICR listed below should be received by no later than the requested OMB approval date. An additional opportunity to comment on this ICR will also be provided when DOL seeks approval under standard PRA clearance procedures.

The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

Agency: Employment and Training Administration.

Title of Collection: Investigative Data Collection Requirements for the Trade Act of 1974 as amended by the Trade and Globalization Adjustment Assistance Act of 2009.

OMB Control Number: 1205-0342.

Affected Public: Individuals or Households; Businesses or other for-profits; and State, Local or Tribal Governments.

Total Estimated Annual Burden Hours: 18,642.

Total Estimated Annual Costs Burden (excluding hourly wage costs): \$0.

Description: On February 17, 2009, the President signed into law the American Recovery and Reinvestment Act (ARRA). Section 221 (a) of Title II, Chapter 2 of the Trade Act of 1974, as amended by ARRA (19 U.S.C. 2271), authorizes the Secretary of Labor and the Governor of each State to accept petitions for certification of eligibility to apply for adjustment assistance. ARRA amended Section 222 of the Trade Act of 1974 to provide for new eligibility criteria designed to expand the number of petitioning worker groups assessed as adversely affected by trade and therefore determined eligible to apply for Trade Adjustment Assistance. To solicit the data needed to address the new eligibility criteria, ETA is significantly expanding the petition and investigation forms currently approved under OMB No. 1205-0342.

The Forms ETA-9042 Petition for Trade Adjustment Assistance and its Spanish translation, and ETA-9042a Solicitud De Asistencia Para Ajuste, establish a format that may be used for filing such petitions. The Department's regulations regarding petitions for worker adjustment assistance may be found at 29 CFR 90. Investigative forms designed to assess eligibility are undertaken in accordance with §§ 222, 223 and 249 of the Trade Act of 1974, as amended (19 U.S.C., 2272 and 2273), are used by the Secretary of Labor to certify groups of workers as eligible to apply for worker trade adjustment assistance. The Forms include: ETA-9043a—Business Confidential Data Request Firms that Produce an Article (CDR-A); ETA-9043b—Business Confidential Data Request Firms that Supply a Service (CDR-S); ETA-9043c—Business Confidential Data Request Firms Who Work on a Contractual Basis; ETA-8562a—Business Confidential Customer Survey; ETA-8562a—Business Confidential Customer Survey; ETA-8562a—Business Confidential Customer Survey First Tier Purchases of Articles; ETA-8562a-1—Business Confidential Customer Survey Second Tier Purchases of Articles; ETA-8562b—Business Confidential Customer Survey Services; ETA-8562c—Business Confidential Customer Survey Firms who Work on a Contractual Basis; ETA-8562d—Business Confidential Customer Survey; and ETA-9118—Business Confidential Information Request.

Why are we requesting Emergency Processing? This collection is submitted on an emergency clearance basis because ARRA (Section 1891) mandates the implementation of the new criteria listed in Section 222 of the Trade Act