Dated: November 20, 2002.

John B. Brown, III,

Deputy Administrator.

[FR Doc. 02–31209 Filed 12–10–02; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Xtreme Enterprises, Inc.: Denial of Request for Registration To Handle List I Chemicals

I. Background

On December 15, 2000, Xtreme Enterprises, Inc., (Respondent) applied to be registered with the Drug Enforcement Administration (DEA) as a distributor of the list I chemical ephedrine. After an investigation by DEA investigators, on April 6, 2001, the Deputy Assistant Administrator, Office of Diversion Control, issued an Order to Show Cause why DEA should not deny Respondent's application. On May 2, 2001, in response to the OSC, Rhonda J. Bryngelson, the owner of Respondent, requested and administrative hearing.

The requested hearing was held in Milwaukee, Wisconsin on November 7, 2001, before Administrative Law Judge Mary Ellen Bittner. At the hearing, each party called witnesses to testify and introduced documentary evidence. After the hearing, each party submitted Proposed Findings of Fact, Conclusions of Law and Argument. On April 3, 2002, the Administrative Law Judge issued her Recommended Rulings, Findings of Fact, Conclusions of Law and Decision, recommending that the Deputy Administrator grant Respondent's application for registration. Neither party filed exceptions to the Administrative Law Judge's Findings.

On May 7, 2002, the Administrative Law Judge certified and transmitted the record to the Deputy Administrator of DEA. The record included the Recommended Rulings, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge, the findings of fact and conclusions of law proposed by all parties, all of the exhibits and affidavits, and the transcript of the hearing sessions.

II. Final Order

The Deputy Administrator does not adopt the Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge. The Deputy Administrator has carefully reviewed the entire record in this matter, as defined above, and hereby issues this final rule and final order prescribed by 21 CFR 1316.67 and 21 CFR 1304.46, based upon the following findings of fact and conclusions.

At the hearing, John N. Uncapher, then chief of the Domestic Chemical Control Unit at DEA, credibly testified that the primary objective of his unit is to reduce or curtail the diversion of listed chemicals and other clandestine lab supplies, register applicants if their registration is consistent with the public interest and stop imports of listed chemicals where there is reason to believe that the imports may be diverted to the unlawful manufacture of controlled substances. After the enactment of the Chemical Diversion and Trafficking Act in 1988 (CDTA), the law imposed reporting, record keeping and import/export notification requirements for regulated transactions in controlled chemicals. The law only applied to bulk ephedrine, however. The law excepted single-entity over the counter (OTC) ephedrine products.

Mr. Uncapher also testified that ephedrine has a therapeutic use in both OTC and legend drug products. Ephedrine is lawfully marketed under the Federal Food, Drug and Cosmetic act for OTC use as a bronchodilator used in the treatment of asthma. Ephedrine is also available OTC in combination with other active ingredients. As a legend drug (*i.e.* dispensed pursuant to a physician's order or prescription,) ephedrine is used in injectable form in hospitals as part of an anethesiology kit. Ephedrine has the beneficial effect of increasing low pressure very rapidly in the event of hypotensive crisis.

By the late 1980's traffickers and clandestine lab operators discovered the ease with which ephedrine could be purchased in large quantities and converted to methamphetamine. In 1994, however, the Domestic Chemical Diversion Control Act of 1993 (DCDCA) removed the record keeping and reporting exemption for single entity ephedrine and required registration of distributors, importers and exporters of all ephedrine products and other list I chemicals.

The passage of the DCDCA led to the increased diversion of pseudoephedrine tablets for the illicit production of methamphetamine. This led to the enactment of the Comprehensive Methamphetamine Control Act of 1006 (MCA), which expanded regulatory control of lawfully marketed drug products containing ephedrine, pseudoephedrine, and phenypropanolamine.

Mr. Uncapher also testified that he had reviewed the file concerning Respondent's application. The file revealed that Respondent's owner informed DEA that the Respondent would distribute ephedrine products to entities that are considered part of the ''non-traditional market'' (*i.e.,* gas stations and convenience stores). Mr. Uncapher also testified that one of Respondent's proposed suppliers of ephedrine is Proactive Labs, Inc., a DEA registered distributor of list I chemicals located in Austell, Georgia. On November 9, 1999 and again on January 24, 2001, Proactive Labs was the recipient of warning letters from DEA informing the company that list I chemicals supplied by the firm had been associated with the illicit production of methamphetamine in various parts of the United States. Mr. Uncapher concluded that Respondent's ephedrine products will likely be diverted to illicit use, and the Respondent would therefore become a major source of listed chemicals for illicit traffickers of methamphetamine.

Guy J. Hargreaves testified by written declaration that he is a Special Agent at DEA and has had considerable experience in the investigation of clandestine methamphetamine laboratories. He routinely conducts nationwide methamphetamine and clandestine laboratory safety presentations to civil groups, anti-drug coalitions, and law enforcement groups on safety awareness, chemical hazards, and the latest intelligence in clandestine laboratory investigations. Mr. Hargreaves testified that until the early 1990's, the methamphetamine trade was fragmented into small organizations dominated by outlaw motorcycle gangs. Afterwards, organized methamphetamine traffickers from Mexico began to monopolize the production and delivery of methamphetamine to make an inexpensive and highly abusable product. An expanded population of methamphetamine abusers quickly realized the potential for easily producing methamphetamine for personal or local use by using the ephedrine/pseudoephedrine reduction technique. As a result, the proliferation of smaller laboratories has reached epidemic proportions, on both the west coast and in several Midwestern states. S/A Hargreaves further testified that most drugs in illicit traffic are products of illicit processing or synthesis. In the methamphetamine trade, chemicals are often accumulated and processed by cooks in small scale production labs or by organized crime groups which operate much larger scale clandestine laboratories.

Mr. Hargreaves also testified that clandestine laboratory operators employ a variety of methods to conceal from law enforcement their purchases of

chemicals and equipment. One common technique is to use unwitting individuals or runners to purchase the chemicals or equipment needed for the laboratory. Mr. Hargreaves also explained the four methods most commonly used in the illicit manufacture of methamphetamine. All four of the techniques utilize 1-ephedrine or d-pseudoephedrine as the precursor chemical. Mr Hargreaves further testified that the number of clandestine laboratory seizures has seen a spiraling increase in recent years. DEA participation in methamphetamine lab seizures has increased from 263 in 1994 to more than 2000 in 1999. He also discussed the hazards to DEA officials in dismantling of clandestine laboratories and great expense to DEA in disposing of the hazardous materials often found there. Interviews that Mr. Hargreaves has conducted with numerous narcotics officers across the nation indicate that the vast majority of these laboratories utilized pseudoephedrine and/or ephedrine from tablets and pills, not bulk powder sources.

Douglas A. Snyder, Drug Science officer within the Drug and Chemical Evaluation Section at DEA, credibly testified by declaration that there are 35 chemicals that are regulated under the Controlled Substance Act's chemical control provisions. The major part of DEA's regulatory concern is with the listed chemicals ephedrine, psuedoephedrine and phenylpropanolamine. All three have therapeutic uses in both over the counter and legend drug products. Methamphetamine also has therapeutic uses, but it also has a high abuse potential. Dr. Snyder further testified that the production of methamphetamine from ephedrine or pseudoephedrine tablets can be accomplished via a simple one step reaction and can be accomplished with little or no chemistry expertise. The controlled substances produced from these chemicals, methamphetamine and amphetamine, have a high abuse potential. The public health consequences of the manufacture, trafficking and abuse of these substances are well know and documented.

Nancy Coffey, a staff coordinator in DEA's Office of Diversion Control, credibly testified by declaration that recent studies show that illicit manufacturers of methamphetamine have returned to the use of ephedrine in the manufacturing process. This probably has occurred as a result of DEA's concentration on the diversion of pseudoephedrine. DEA enforcement efforts are designed to combat the distribution by non-traditional establishments of list I chemical products, commonly referred to as ''gray market'' products. The distribution chain for the gray market products most commonly consists of small retail establishments, including, but not limited to, liquor stores, head shops, mini-marts, beauty parlors, convenience stores and video rental stores that purchase and sell ephedrine and pseudoephedrine over-the-counter products in quantities that far exceed what would be necessary to meet legitimate demand. Ms. Coffey concluded that such products will likely be diverted to illicit use, and Respondent could therefore become a major source of listed chemicals for illicit traffickers of methamphetamine.

Mark J. Rubbins testified by declaration that he is a Staff Coordinator in the Domestic Control Unit of DEA. He explained that DEA distinguishes the distribution practices of what is referred to as the ''traditional'' market versus the ''non-traditional'' market. Traditional outlets are typically large chain grocery stores such as Giant, Safeway and Food Lion, or nationally recognized pharmacy chains like Rite Aid, Eckerts and CVS. The traditional products are also sold in larger convenience stores such as 7–11 and Dairy Mart, as well as large retail outlets such as Walmart and K-Mart. Mr. Rubbins further testified that in response to DEA enforcement efforts, more and more traditional firms have discontinued their marketing of 60 mg. pseudoephedrine and similar OTC medications in bottle sizes with a single-active ingredient. The traditional manufacturers have also begun packaging their OTC products in small quantities (*i.e.,* blister packs,) and have maintained a 30 milligram strength for pseudoephedrine products. While even smaller blister packs are increasingly diverted to illicit uses, they are not as attractive to traffickers as OTC products packaged in large bottle sizes, with a single active ingredient. Mr. Rubbins also testified that Respondent would be part of what DEA considers the non-traditional market, in that it is a retail distributor that specializes in the sale of sundry items, not OTC pharmaceutical products. Based upon his review of Respondent's file, it appears that some of Respondent's customers have already requested that the firm carry 25 milligram tablets in 60 count bottles. Mr. Rubbins found this factor significant in that the customers at issue requested the larger packaging that is not normally seen in traditional retail establishments. This led Mr. Rubbins to the conclusion that Respondent plans to market its products to the non-traditional market, and would therefore become a major source of listed chemicals for illicit traffickers of methamphetamine.

Rhonda Bryngelson, Respondent's owner, testified credibly on behalf of the Respondent. She is high school educated, and has not taken any business courses. She has no prior experience handling list I chemicals. Mrs. Bryngelson testified further that she is the sole owner of the Respondent and has been in business since January 2001. Her business is primarily engaged in the sale of various novelty items. She previously worked for her brother-in-law's company Quality Snacks, where she delivered beef jerky for the company. Quality Snacks did not sell ephedrine products. While working for her brother-in-law, Mrs. Bryngelson also made deliveries for Quality Snack's wholesaler, Mid-America. Although she made deliveries of ephedrine products on behalf of Mid-America, she did not know whether Mid-America or her brother-in-law were licensed to sell these products. Mrs. Bryngelson testified that when she made the above deliveries of listed chemicals, they were usually in 50-count boxes, in packets of six. She also delivered, however, ''a blue or green'' 60-count bottle, but she was unaware of the product names.

The government also called James Barbe as a witness. At the time of his testimony, Mr. Barbe was a Diversion Investigator with DEA's Milwaukee office. Mr. Barbe credibly testified that Mrs. Bryngelson submitted on behalf of her company an application for DEA registration as a distributor of the list I chemical ephedrine.[1] The Respondent's listed address on the application was in Merton, Wisconsin. The application was received by the Milwaukee Resident Office. D/I Barbe further testified that he was assigned to investigate the Respondent's application. The Respondent's proposed registered address is located in a residential location owned by Mrs. Bryngelson's sister, Theresa, and her husband Bruce Johnson. Mrs. Bryngelson stores her novelty products in a basement at that location. The residence is located in a rural community, and Mrs. Bryngelson does not reside at that location.

In an interview conducted of Mrs. Bryngelson by D/I Barbe, Mrs. Bryngelson stated that:

- She had no experience with over the counter medications or listed chemicals.

[1] At the hearing, Mrs. Bryngelson stated that she believed that she had applied for registration to sell both ephedrine and pseudoephedrine.

• Some of her customers had requested that the Respondent supply listed chemical products in addition to her normal product line, because they wanted her to be their sole source.

• When asked which listed chemical products she wished to distribute, she replied that she wanted to sell those in ''the green and blue bottle'' and ''Green E'' from Proactive Labs.

• She estimated that Respondent's percentage of sales of listed chemicals would be five percent of its total sales.

• In response to questions regarding the security for Respondent's proposed location, she said that she would use a locked door.

• She informed D/I Barbe that the proposed location is in a secluded 360 acres in the middle of a cornfield, and that the location never had break-ins or the like.

After a visit to Respondents location, D/I Barbe testified that he did not recall seeing a bolt lock on the door leading to the basement area. Mrs. Bryngelson testified that no alarm system or any electronic security system had been set up at the proposed registered location. She also testified that she was willing to have as much security installed as DEA required.

D/I Barbe also testified that he reviewed ''suspicious order'' procedures with Mrs. Bryngelson. He also discussed matters involving background checks on customers. D/I Barbe testified that Mrs. Bryngelson was unaware at that time of how to address suspicious orders. Mrs. Bryngelson also testified that some of her accounts had threatened to discontinue their business with Respondent unless she was able to supply listed chemical products. However, she was only able to identify three of the twenty-customers disclosed to DEA that had actually threatened such action. She also testified that she had recently added 80 additional customers, and that only ''a couple'' had been interested in obtaining ephedrine.

D/I Barbe also testified that he had asked Mrs. Bryngelson how many bottles she planned on selling, and she replied that it would be approximately twelve bottles per week Mrs. Bryngelson testified at the hearing, however, that this estimate was ''a wild guess.''

D/I Barbe further testified that he had obtained a list of Respondent's customers, and he verified the identity of these customers through telephone calls and visits. He found that most of Respondent's accounts were gas stations. D/I Barbe further testified that Respondent's customers were part of what DEA considers the non-traditional market, in that they were retail distributors that specialized in the sale of sundry items, not OTC pharmaceutical products. The customers were comprised primarily of gas stations and convenience stores. D/I Barbe also testified that some of Respondent's customers had already requested that Respondent carry 25 milligram tablets in 60 count bottles of ephedrine. D/I Barbe explained that these requests were significant in that the customers at issue had already begun requesting list I chemicals from the Respondent, a specific type of product, in packaging that is not normally seen in traditional retail establishments.

The Government also presented the transcribed testimony of Jonathan Robbin, of Ricercar, Incorporated, in Bethesda, Maryland. Mr. Robbin is a consultant in marketing information systems, databases and in the building of analytical models to assist businesses in decision making. Mr. Robbin provided the transcribed testimony on behalf of the Government in a previous DEA proceeding involving Branex, Incorporated. He was offered as an expert in statistical analysis, specifically in multi-varient statistics and the processing of population and economic census data. Mr. Robbin was also offered as an expert in quantitative marketing research specifically with respect to retail marketing and targeting. Mr. Robbin testified that according to the economic census, the normal or traditional place where consumers would purchase non-prescription drugs would be in drug stores, supermarkets and discount merchandise houses. Mr. Robbin testified that the expected sale of these products at convenience stores and convenience stores attached to gas stations were not significant enough to warrant inclusion in the most recent census data form for cold, sinus and allergy products. Mr. Robbin continued that such products represented ''a very small part of [the] total line of goods'' for convenience stores, whether or not they sell gasoline.

Based upon the above, the Deputy Administrator will now consider the factors used by DEA to determine the public interest. Under 21 U.S.C. 823(h), the Attorney General shall register an applicant to distribute a list I chemical unless the Attorney General determines that the registration of the applicant is inconsistent the public interest.[2] In considering the public interest, the Deputy Administrator shall consider:

1. Maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels;

2. Compliance by the applicant with applicable Federal, State, and local laws;

3. Any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;

4. Any past experience of the applicant in the manufacture and distribution of chemicals and

5. Such other factors as are relevant to and consistent with the public health and safety.

Consideration of the first factor weighs against Respondent. Although Mrs. Bryngelson agreed to provide increased security at the residence where list I chemicals will be stored, she appears to have only a rudimentary knowledge of what would constitute a suspicious order.

With regard to the second factor, there was no evidence that the Respondent has failed to comply with Federal, State or local law. As for the third factor, there is no evidence that Mr. Bryngelson has any prior convictions related to controlled substances or chemicals. Accordingly, the second and third factors weigh in Respondent's favor. Addressing the fourth factor, Mrs. Bryngelson has no experience in the manufacture or distribution of chemicals, which weighs against Respondent.

With regard to the fifth factor, many considerations weigh heavily against registering Respondent as a distributor of list I chemicals. Virtually all of Respondent's's customers, consisting of gas stations and convenience stores, are considered part of the gray market, in which large amounts of listed chemicals are diverted to the illicit manufacture of amphetamine and methamphetamine. Some of these customers have already requested 60 count bottles of ephedrine, the favored packaging of illicit methamphetamine manufacturers. Mrs. Bryngelson also appears to have little idea of the extent of her market for listed chemicals. She testified that she expected to sell approximately 12 bottles of ephedrine each week, but she admitted that this was a ''wild guess.''

The Deputy Administrator finds that Mrs. Bryngelson's lack of a criminal record, compliance with the law and willingness to upgrade her security system are far outweighed by her lack of experience with selling list I chemicals and the fact that she intends to sell ephedrine almost exclusively in the gray market. Accordingly, the Deputy Administrator of the Drug Enforcement Administration, pursuant to the

[2] This function has been redelegated to the Deputy Administrator of DEA.

authority vested in him by 21 U.S.C. 823 and 824 and 28 CFR 0.100 and 0.104, hereby finds that registration of Respondent as a distributor of list I chemicals is not in the public interest. The Deputy Administrator hereby orders that the application for a DEA certificate of registration and any requests for renewal or modification submitted by Respondent Xtreme Enterprises be, and hereby are, denied.

Dated: December 2, 2002.

John B. Brown, III,

Deputy Administrator.

[FR Doc. 02–31210 Filed 12–10–02; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF LABOR

Pension and Welfare Benefits Administration

Proposed Extension of Information Collection Request Submitted for Public Comment; ERISA Summary Annual Report

AGENCY: Pension and Welfare Benefits Administration, Department of Labor.

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA 95). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Pension and Welfare Benefits Administration is soliciting comments on the proposed extension of the ERISA Summary Annual Report requirement.

A copy of the information collection request (ICR) can be obtained by contacting the individual shown in the Addresses section of this notice.

DATES: Written comments must be submitted to the office shown in the **ADDRESSES** section on or before February 10, 2003.

ADDRESSES: Gerald B. Lindrew, Department of Labor, Pension and Welfare Benefits Administration, 200 Constitution Avenue NW., Washington, DC 20210, (202) 693–8410, FAX (202) 693–4745 (these are not toll-free numbers).

SUPPLEMENTARY INFORMATION:

I. Background

Section 104(b)(3) of ERISA and regulations published at 29 CFR 2520.104b-10 require, with certain exceptions, that administrators of employee benefit plans furnish participants and beneficiaries annually with material that fairly summarizes the information included in the plan's latest annual report. The regulation prescribes the format for the summary annual report (SAR), and requires that the SAR be provided within nine months after the close of the plan year.

The SAR is required to be provided to plan participants and beneficiaries to ensure that they are informed concerning the financial operation and condition of their plans. These disclosures to plan participants also assist the Department in its enforcement responsibilities by providing participants with sufficient information to exercise their rights under ERISA.

II. Review Focus

The Department of Labor (Department) is particularly interested in comments that:

- 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.

III. Current Actions

The Office of Management and Budget's (OMB) approval of this ICR will expire on February 28, 2003. After considering comments received in response to this notice, the Department intends to submit the ICR to OMB for continuing approval. No change to the existing ICR is proposed or made at this time.

Agency: Pension and Welfare Benefits Administration, Department of Labor.

Title: ERISA Summary Annual Report.

Type of Review: Extension of a currently approved collection of information.

OMB Number: 1210–0040.

Affected Public: Individuals or households; Business or other for-profit; Not-for-profit institutions.

Respondents: 815,114.

Responses: 304,196,000.

Estimated Total Burden Hours: 325,240.

Estimated Total Burden Cost (Operating and Maintenance): $142,448,000.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: December 4, 2002.

Gerald B. Lindrew,

Deputy Director, Office of Policy and Research, Pension and Welfare Benefits Administration.

[FR Doc. 02–31217 Filed 12–10–02; 8:45 am]

BILLING CODE 4510–29–M

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–302]

Florida Power Corporation; Crystal River Unit 3; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (NRC) is considering issuance of an exemption from Title 10 of the Code of Federal Regulations (10 CFR) part 55, section 55.59(c) for Facility Operating License No. DPR–72, issued to Florida Power Corporation (the licensee), for operation of Crystal River Unit 3 (CR–3), located in Citrus County, Florida. Therefore, as required by 10 CFR 51.21, the NRC is issuing this environmental assessment and finding of no significant impact.

Environmental Assessment

Identification of the Proposed Action

The proposed action would constitute a one-time exemption to allow the licensed operator requalification examinations for CR–3 to be rescheduled. The requested exemption would extend the completion date for the examinations from December 31, 2002, to February 28, 2003.

The proposed action is in accordance with the licensee's application for exemption dated November 18, 2002.