Citizen Petition

Date: June 20, 2024

The undersigned submits this petition under 21CFR10.30 and 21FCR314.161 of the Code of Federal Regulations to request the Commissioner of Food and Drugs to take a form of administrative action.

A. Action Requested

The petition requests the Commissioner to take administrative action, specifically a determination whether the listed drug (Lunelle) that has been voluntarily withdrawn from sale was withdrawn for safety or effectiveness reasons.

B. Statement of Grounds

The listed drug with the brand name, Lunelle, contains estradiol cypionate and medroxyprogesterone acetate, with the following dosage 5mg/0.5ml and 25mg/0.5ml, respectively, and was used as an intramuscular injectable.

Lunelle, made by Pharmacia & Upjohn, was approved for marketing in the US on October 5, 2000, under NDA 020874. It was the first-to-market monthly injectable. Lunelle was well received and considered to be 99% effective in preventing pregnancy.

In October of 2002, Pharmacia Corp. started a voluntary recall of all prefilled syringes of Lunelle stating, “a lack of assurance of full potency and possible risk of contraceptive failure." (please see Attachment3 for details). The company also halted manufacture of vials of Lunelle that were NOT part of the voluntary recall possibly because of confusion as to which injection was given to a patient. At no point were the vials of Lunelle ever recalled, and the company made this statement, “The concentration of estradiol cypionate and medroxyprogesterone acetate contained in the vials is sufficient to result in expected contraceptive efficacy.”

Pharmacia continued to not manufacture Lunelle, and subsequently it was voluntarily withdrawn from the market. Docket No. 2004N–0159, dated May 4, 2004, contained two statements regarding the collection of NDAs and ANDAs withdrawn from market at that time which included Lunelle. The first statement was under Summary, “The Food and Drug Administration (FDA) is withdrawing approval of 92 new drug applications (NDAs) and 49 abbreviated new drug applications (ANDAs). The holders of the applications notified the agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn”. The second statement was under Supplementary Information, “The holders of the applications listed in the table in this document have informed FDA that these drug products are no longer

marketed and have requested that FDA withdraw approval of the applications. The applicants have also, by their requests, waived their opportunity for a hearing". Lunelle was hereby withdrawn, effective June 4, 2004 (please see Attachment2).

Of note, Pharmacia merged with Pfizer in 2003, and Pfizer, as of today, has 2 products on the US market, 1) Depo-provera (medroxyprogesterone acetate injectable suspension), and 2) Depo-estradiol (estradiol cypionate injection). These are the two APIs of Lunelle.

It is the belief in this petition that Lunelle was not voluntarily withdrawn from the US market for safety or effectiveness reasons. Again, the petition is requesting the Commissioner of Food and Drugs to make a determination about the drug product Lunelle.

C. Environmental Impact

The petition is making a claim of categorical exclusion. This petition is stating compliance with the categorical exclusion criteria found in 21CFR25.31 and to the applicant's knowledge, no extraordinary circumstances exist.

D. Economic Impact

Economic impact information will be submitted upon request of the commissioner.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

(signature)

Sarah A. Norring, Ph.D. (name of petitioner)

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Attachment1_Citizen Petition 240620
Attachment2_FedReg Lunelle
Attachment3_Lunelle Voluntary Recall