PHARMACIA

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Pharmacia Corporation
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Kalamazoo, Michigan 49001

URGENT DRUG RECALL

*** All Lunelle™ Prefilled Syringes ***

NDC Number	Product	Lot Number	Expiration Date
0009-3484-06	LUNELLE™ Monthly Contraceptive Injection (medroxyprogesterone acetate and estradiol cypionate injectable suspension), 25 mg/5 mg per 0.5 mL, 0.5 mL syringe	II0702	04/2003
		IJ0602	04/2003
		IJ0151	05/2003
		IJ1394	05/2003
		IK0786	05/2003
		JA0630	05/2003
		JA1809	05/2003
		JC0691	06/2003
		JD1419	06/2003
		JD1420	06/2003
		JF0689	05/2004
		JG0301	05/2004
		JG0907	06/2004
0009-3484-98	LUNELLE Monthly Contraceptive Injection (medroxyprogesterone acetate and estradiol cypionate injectable suspension), 25 mg/5 mg per 0.5 mL, 0.5 mL syringe **(physician sample)**	IJ0656	04/2003
		IJ1391	05/2003
		IK0779	05/2003
		JA1805	05/2003

Dear Physician:

Pharmacia Corporation is voluntarily recalling Lunelle prefilled syringe lots due to a lack of assurance of full potency and possible risk of contraceptive failure. A recent review of production records indicates the potential for sub-potency. Therefore, as a precaution, we are voluntarily recalling all Lunelle prefilled syringe lots currently on the market and the product will be unavailable for the immediate future. No other Pharmacia products are affected by this recall. This recall is being conducted with the knowledge of the Food and Drug Administration and has been designated a Class I recall.

A sub-potent injection of Lunelle may not be effective in the prevention of pregnancy. Therefore, we are instructing physicians who have administered Lunelle prefilled syringes to contact all patients and recommend the use of an additional barrier method of birth control (such as condoms, diaphragm, or spermicide), before beginning a new form of hormonal contraception. We are also recommending that physicians perform a pregnancy test for patients currently on Lunelle. Pharmacia will provide suitable pregnancy test kits to physicians for use with patients currently on Lunelle.

Pharmacia will also supply condoms to physicians to provide to Lunelle patients free of charge. To request pregnancy test kits or condoms, please call 866-264-9233.

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Physicians should also be aware that Pharmacia has issued a press release and is conducting additional outreach efforts regarding this recall, advising women who have been using Lunelle as their contraceptive to seek the advice of their healthcare professional. To assist physicians in communicating with patients regarding this recall, we are enclosing a sample patient notification template.

Please complete the steps listed below to assist us in completing this recall. **It is important that you carry out these instructions.** FDA regulations (21 CFR Part 7.49) state: "Consignees that receive a recall communication should immediately carry out the instructions set forth by the recalling firm…"

ACTION:

1. Contact patients regarding the recall as instructed above.
2. Discontinue using and dispensing all Lunelle prefilled syringe lots and promptly return any inventory according to the instructions below.
3. Perform a physical count of your inventory for the recalled lots and complete the enclosed Business Reply Card.
4. Mail the postage paid Business Reply Card **even if you do not have any of the affected lots.** Your response, even if you do not have any recalled product, is very important to both us and the FDA in monitoring the effectiveness of this recall.

RETURN OF RECALLED PRODUCT:

If you have any of the recalled products to return, please do so as follows:

a. Complete the enclosed packing slip and include it with your return.
b. Use the pre-paid shipping label provided and forward to:

NNC Group
5250 West 76th Street
Indianapolis, IN 46268

Your account will be credited for the returned product. Please allow 6-8 weeks for processing. To help assure prompt issue of credit, do not include any other product with your return. For questions regarding the return of recalled product, please contact NNC Group toll free at 866-264-9233.

If you have product or medical questions regarding this recall, please call 800-323-4204, 8:00 AM to 5:00 PM ET. We appreciate your cooperation and sincerely regret any inconvenience caused by this action.

Sincerely,

John Nadelin
Associate Director, Corporate Quality Assurance