Indiana State Department of Health
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Mitchell E. Daniels, Jr.
Governor

Gregory N. Larkin, M.D., F.A.A.F.P.
State Health Commissioner

DATE: August 1, 2011

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: FDA News Release on Evital

SUGGESTED ACTION: **Information provided in case of consumer inquiry.**

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FDA PRESS RELEASE

(Logo: http://photos.prnewswire.com/prnh/20090824/FDALOGO)

For Immediate Release: August 1, 2011

Media Inquiries: Shelly Burgess 301-796-4651; shelly.burgess@fda.hhs.gov

Consumer Inquiries: 888-INFO-FDA

Unapproved emergency birth control medicine possibly in U.S. distribution may be ineffective and unsafe

The U.S. Food and Drug Administration (FDA) is warning U.S. consumers not to use the emergency birth control medicine labeled as Evital. These products may be counterfeit versions of the "morning after pill" and may not be safe or effective in preventing pregnancy.

Evital has not been approved by the FDA for use in the United States.

This potentially ineffective and suspect counterfeit emergency birth control may also be in distribution in some Hispanic communities in the United States.

The packaging label of the potentially ineffective and suspect counterfeit version says, "Evital Anticonceptivo de emergencia, 1.5 mg, 1 tablet", by "Fluter Domull" :

- Contact your doctor or health care professional if you have taken Evital labeled as the 1.5 mg tablet and experienced any problems.
- There are FDA-approved emergency birth control medicines available both with a prescription, and over-the-counter without a prescription (if you are 17 years old or older).
- You should talk with a doctor, pharmacist, or health care professional to find the FDA-approved emergency birth control medicine best for you.

FDA is asking for help from consumers who have information about Evital. Please send an email to CDER_Ingredient_Adulteration@fda.hhs.gov to provide information or if you have more questions.

Any information received is confidential and will be used only to help in FDA's effort to remove the potentially unsafe and ineffective versions from the U.S. marketplace.

Health care professionals and consumers are asked to report adverse events related to the use of suspect counterfeit versions of Evital to the FDA's MedWatch Safety Information and Adverse Event Reporting Program either online, by regular mail, by fax, or by phone.

- Complete and submit the report online: www.fda.gov/MedWatch/report.htm
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

For more information about counterfeit medicine, click on link below:

http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/CounterfeitMedicine/default.htm

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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