



DEPARTMENT OF HEALTH & HUMAN SERVICES

No Purge Necessary

Public Health Service  
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Food and Drug Administration  
Rockville MD 20857

**WARNING LETTER**  
**VIA EXPRESS MAIL**

APR 4 2000

Internet Birthcontrol.com, Inc.  
1269 56<sup>th</sup> Street #18037  
Delta, BC V4L 2M4  
Canada

Dear Chief Executive:

We have evidence that your firm is soliciting the citizens of the United States to purchase various uncleared medical devices. For example, many of the devices used to prevent pregnancy and disease transmission, which you offer for sale on your Internet site, <http://www.birthcontrol.com>, require marketing clearance and may not be legally marketed in the United States (US) without such clearance. These devices are:

The Lea Shield (Barrier)	Pantycondom
Persona Contraceptive System	Ezon Male Condom
Ladycomp and Babycomp Computers	The Unisex Condom
Ovu-Trac	The Dental Dam
Oves Contraceptive Cap	

Under a U.S. law, the Federal, Food, Drug and Cosmetic Act (Act), these products are considered to be medical devices because they are used to diagnose or treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices obtain marketing clearance for their products from the Food and Drug Administration (FDA) before they may offer them for sale. This helps to protect the public by ensuring that new medical devices are shown to be either safe or effective or substantially equivalent to other devices already legally marketed in this country.

Our records do not show that you obtained marketing clearance before you began offering your products for sale. Because you do not have marketing clearance, marketing your products is a violation of the law. In legal terms, the products are considered adulterated under section 501(f)(1)(B) and misbranded under section 501(o) of the Act. Your products are adulterated under the Act because you did not obtain premarket approval based on information developed by you that shows your devices are safe and effective. Your products are misbranded under the Act because you did not submit information that shows your devices are substantially equivalent to other devices that are legally marketed.

We are taking steps to warn our citizens that these devices have not been cleared for marketing in this country and may not be legally imported.

Page 2 – CEO, Birthcontrol.com, Inc.

With copies of this letter, we are also advising the regulatory device officials in Canada of these violations.

Given the serious nature of these violations, these products may be detained upon entry into the U.S. until the violations are corrected.

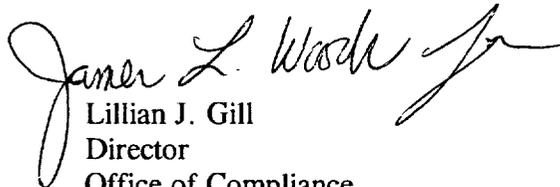
Please notify this office within fifteen (15) working days from the receipt of this letter as to the specific steps you intend to take to correct these violations.

Your reply should be addressed to the following:

US Food and Drug Administration  
ATTN: OB/GYN, GI, GU Branch  
2094 Gaither Road, HFZ-332  
Rockville, Maryland USA 20850

Please address your response and any questions to Paul F. Tilton, Acting Chief, OB/GYN, Gastroenterology and Urology Branch, at the letterhead address, at (301) 594-4616 or by FAX at (301) 594-4638.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Lillian J. Gill". The signature is fluid and cursive, with a large initial "L" and "J".

Lillian J. Gill  
Director  
Office of Compliance  
Center for Devices and  
Radiological Health