

Exhibit 5-15
MODEL COMPREHENSIVE STATEMENT*
Administrative Detention of Devices

Date

Ace Plastic Co.
11124 Railroad Street
Ogallala, Nebraska 69150

Dear Sir:

The following is a Comprehensive Statement of the Basis for Detention Order DN 60011.

FDA Investigator _____ observations:

Black unidentified spots on the needles and holes in the individual protective packaging of the sterile 2cc syringe led him/her to believe that the devices are adulterated and misbranded resulting in issuing Detention Order number DN 60011.

_____made these observations during his/her (date) inspection of your establishment.

The black spots on the needles and holes in the packages lead us to believe the product is adulterated within the meaning of (1) Section 501(a)(2)(A) of the Federal Food, Drug, and Cosmetic Act (the Act) in that the device has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health; and (2) within the meaning of Section 501(c) of the Act in that its quality falls below that which it purports or is represented to possess. Further, these same observations lead us to believe that the product is misbranded per Section 502(a) of the Act because the label states the product to be sterile and the holes in the protective wrapper allow the product to be exposed to contamination.

*To be used when the detention order (FDA 2289 Detention Notice) may not serve as the Comprehensive Statement because the "reason for detention" is not described in sufficient detail. When the detention order may serve as the Comprehensive Statement, the letter need only include a copy of the detention order and reference the "reason for detention" as the Comprehensive Statement.