

FDA cracks down on unapproved ear drops

July 1 2015

The Food and Drug Administration says it plans to crack down on unapproved prescription ear drops often given to young children suffering from ear infections.

The agency published a memo Tuesday warning manufacturers of the drops to cease production or they could face criminal proceedings. The drops at issue contain ingredients like benzocaine, antipyrine and [zinc acetate](#).

Because the products are not overseen by FDA regulators they could be contaminated or manufactured incorrectly. The agency notes that there are numerous FDA-approved ear drops, so "little or no impact on patients" is expected from removing the products from the market.

Companies that want federal approval for their drugs must submit an FDA application for review. FDA approves drugs based on studies on their safety and effectiveness.

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