

SAMPLE TESTIMONY TO THE FDA

TO: [COMPLIANCE OFFICER'S NAME], Compliance Officer, U.S. Food and Drug Administration, 4040 N. Central Expressway, Suite 300, Dallas, TX 75204

EMAIL: XXXXXXX@fda.gov.

FROM: Jane Johnson, 708 Can't Afford Meds Street, Provo, UT 84603

SUBJECT: Release personal drug order testimony, [REFERENCE # ON YOUR NOTIFICATION]

You have detained or refused medication that I ordered, [DRUG NAME], [DRUG STRENGTH], [DRUG QUANTITY], and I'm exercising my rights to appropriate due process to challenge your decision. My health is at risk because of your action. I'm providing the testimony herein to challenge your decision so that you release my medication to me immediately.

My imported medication is for personal use only.

I have a valid prescription from my doctor. Please see the attached prescription as evidence.

You assert that the medication I ordered is reimported. A 'reimported' drug is one that was manufactured in the United States, made under the jurisdiction of the FDA, and in compliance with U.S. law. These drugs are clearly approved, safe, and effective, according to the FDA. Also, the manufacturer is clearly registered with the FDA and has listed the U.S. identical version of this drug. Congress never intended Section 801 (d) to apply to *individuals buying American-made medications from a foreign pharmacy for their own use*. As you know, I am only able to afford this imported medication dispensed by a foreign pharmacy (at much lower prices).

The Congressional record on the legislation giving rise to Section 801 (d) focused solely on preventing the re-importation of medication for *commercial resale* in the United States. I've ordered this medication for myself, as evidenced by the quantity and my prescription, and will not distribute it to any other person for any reason.

I cannot afford this medication at my local pharmacy. Therefore, it is unavailable to me in the United States. This justifies you exercising enforcement discretion and releasing the medication to me.

This medication was dispensed by a pharmacy in [COUNTRY] called [PHARMACY NAME]. That pharmacy is licensed by the [NAME OF THE LICENSING AUTHORITY], [LICENSE # XXXXX].

If you do not release it to me I could become sick and even die.

The World Health Organization views access to medicine as a human right. Since I cannot afford this medication in the United States under any ordinary and sanctioned healthcare system, I do not have access to it here.

The medication I ordered is an FDA-approved drug. Since I have a prescription and a copy of the U.S. label, I have proven that I'm under the care of a licensed practitioner and I know how to use the

medication. Moreover, I have ordered the medication from a licensed pharmacy in [COUNTRY]. Pursuant to the evidence and reasons given above, I believe my testimony overcomes the FDA's justifications for refusing my medication order and ask that you release it to me. If you don't then my health may be jeopardized because I can't afford it locally. Please be compassionate. Imagine if I was a member of your family and could not afford my medication. Depriving me of this medication would go against your stated mission to protect public health.

You can contact me at [YOUR PHONE NUMBER] or reply by email.

Sincerely,

Jane Johnson