

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 appears to be a misbranded drug as the reason to postpone or deny its importation. Please consider why that is not a legitimate or fair reason. Since this drug was dispensed to me pursuant to a valid prescription by a licensed practitioner in the U.S., the drug is exempted by FDA regulation from the "adequate directions for use" requirement. [21 CFR 201.100].

Furthermore, I have the benefit of the FDA's guidelines for adequate directions for use and the drug warnings pertaining to this medication. As evidence, please see the attached label, which is the official FDA-approved U.S. label. [You can search for your drug's label at <http://dailymed.nlm.nih.gov/dailymed/index.cfm>.] I have the requisite information I need to safely use this medication.

You assert that the medication I ordered appears to be an unapproved drug as the reason to postpone or deny its importation. Please consider why that is not a legitimate or fair reason. An 'unapproved' drug is one that was not manufactured in an FDA registered establishment. I believe that this drug was made in an establishment registered with the FDA.

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 was manufactured in an FDA-registered establishment. 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