



DEC 11 2013

Food and Drug Administration
10903 New Hampshire Ave
Building 51
Silver Spring, MD 20993

Nuo Wang, Ph.D
Managing Member
Salus Pharma, LLC
11 Deer Park Drive, Unit 120
Monmouth Junction, NJ 08852

Re: Docket No. FDA-2013-P-0768

Dear Dr. Wang:

I am writing to inform you that the Food and Drug Administration (FDA or Agency) has not yet resolved the issues raised in your citizen petition received on June 18, 2013. Your petition requests that the Agency determine whether Zefazone (cefmetazole sodium) injection, equivalent (EQ) 1 gram (gm) base/vial and EQ 2 gm base/vial have been voluntarily withdrawn for safety or effectiveness.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Jane Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research