DEPARTMENT OF HEALTH & HUMAN SERVICES

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

March 24, 2014

Russell Bodoff
President & CEO
National Home Infusion Association
100 Daingerfield Road
Alexandria, VA 22314

Dear Mr. Bodoff,

Thank you for your letter of February 19, 2014 concerning FDA's recent communications to purchasers encouraging them to purchase the compounded drugs they need to meet the medical needs of their patients from registered outsourcing facilities. You raise concerns that by suggesting that healthcare providers should purchase compounded drugs from registered outsourcing facilities, FDA is implying inaccurately that registered outsourcing facilities are appropriate for all compounding needs. You also express concerns that FDA will impose a sterility testing requirement as part of the current good manufacturing practices (CGMP) requirements for registered outsourcing facilities that would affect access to certain compounded drugs that are used by home infusion and other healthcare providers. You state that if FDA imposes such a requirement, certain drugs used for parenteral nutrition, pain management, antibiotic treatments, and oncology treatments would only be available from section 503A regulated facilities, which you describe as traditional pharmacies.

FDA appreciates your taking the time to bring your concerns to our attention. As you know, registered outsourcing facilities are subject to CGMP requirements. In addition, they must report adverse events to FDA, label their products with certain information, and meet certain other conditions if they are to qualify for the exemptions from the FDA drug approval and adequate directions for use requirements of the FD&C Act. Once an outsourcing facility is registered, the facility is subject to inspection by FDA according to a risk-based schedule.

Because compounders are not required to register as outsourcing facilities, it is hoped that market forces will create demand for products made at outsourcing facilities that operate under CGMP requirements, are overseen by FDA, and that meet certain other conditions such as reporting adverse events and labeling their products with information important to purchasers. FDA sent the letters to purchasers and to the states to encourage them to purchase compounded drugs from the new category of outsourcing facilities that is designed to provide purchasers of compounded drugs with a greater assurance of high quality products.

FDA recognizes that traditional compounding pharmacies will continue to play an important role in providing necessary medications to patients by compounding drugs to fill prescriptions for identified individual patients whose needs cannot be met by an FDA-approved product.

With regard to your concern regarding sterility testing requirements that might be applicable to outsourcing facilities, FDA is developing a draft guidance that will describe FDA's current expectations regarding compliance with CGMP requirements for outsourcing facilities, and will publish that draft guidance for public comment. If you have comments on how sterility testing or other CGMP issues are addressed in that draft guidance, you can provide comments to us that will be taken into account in developing a final guidance.

We hope you will encourage all your members, regardless of whether they chose to register as outsourcing facilities, to adhere to the highest standards of quality and safety when they compound medications. During FDA inspections of sterile compounding facilities over the past year, FDA has observed many significant deficiencies in sterile compounding practices.[1] Since the fungal meningitis outbreak, as of March 6, 2014, thirty-three firms have conducted recalls overseen by FDA and seven firms have conducted recalls overseen by states. In addition, since September 26, 2012, FDA is aware that twenty-eight firms ceased sterile operations, in some cases voluntarily after FDA inspections, and in other cases due to partial or full shutdowns imposed by state licensing authorities. Problems with compounding firms continue to be identified. Compounders need not and indeed should not wait until contamination or an adverse event associated with their products are reported, nor should they wait for an FDA or State inspection to look at whether their operations meet appropriate standards to make compounded drugs and particularly, sterile drugs.

Trade associations such as NHIA can play an important role in encouraging members of the compounding community to take steps to critically assess their operations and bring them up to the standards necessary to produce quality products. We stand ready to work with you in this important effort.

Sincerely,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

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[1] *See* Compounding: Inspections, Recalls, and other Actions Webpage, at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339771.htm (Jan. 15, 2014).