

----- Original Message -----

**From:** "Walsh, Sandy" <Sandy.Walsh@fda.hhs.gov>

**To:** "'Melissa Davis'" <editor@thestreetsweeper.org>

**Cc:**

**Sent:** Tue, 3 Jan 2012 12:02:20 -0500

**Subject:** RE: reporter seeking information about approved uses of acthar

The approval of this product for this particular use predates the modern FDA "efficacy" requirement. For that reason, we feel that it is best to stick to the exact wording used in the label (i.e., induce a diuresis or a remission of proteinuria) and not say that they treat the disease.

[Are you asking about any specific example of promotion of this product, I'm just curious what sparked your interest in this topic?](#)

*Sandy Walsh FDA Office of Public Affairs 301-796-4669*

*sandy.walsh@fda.hhs.gov*

Not sure which press officer to contact? See FDA Press Beats at:

<http://www.fda.gov/NewsEvents/Newsroom/MediaContacts/default.htm>

**From:** Melissa Davis [mailto:editor@thestreetsweeper.org]

**Sent:** Thursday, December 22, 2011 10:46 AM

**To:** Walsh, Sandy

**Subject:** reporter seeking information about approved uses of acthar

Ms. Walsh,

I am seeking some clarification about the approved uses for a drug called

Acthar. According to the label, Acthar can be used "to induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus." Does this automatically mean that Acthar can be promoted as an on-label treatment for "idiopathic membranous nephropathy?" So far, I've received conflicting responses to this question. Thanks so much for any insight that you can provide.

Best,

Melissa Davis

Senior Editor

TheStreetSweeper

(405) 227-0070