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REP. WAXMAN REQUESTS FDA INVESTIGATION OF EFFECTIVENESS OF PHENYLEPHRINE ORAL NASAL DECONGESTANTS

WASHINGTON, DC — Today Rep. Henry A. Waxman called on the Federal Food and Drug Administration (FDA) to investigate whether the oral nasal decongestant phenylephrine is effective.

"While I applaud the much-needed efforts to combat the methamphetamine epidemic, we cannot let companies market ineffective products as an alternative to drugs that are now behind the counter," said Rep. Waxman. "FDA needs to ensure consumers that phenylephrine oral nasal decongestants will safely and effectively relieve their symptoms."

The 2006 reauthorization of the Patriot Act contained anti-methamphetamine legislation that requires all products containing pseudoephedrine — one of the ingredients used to make methamphetamines — to be moved behind the counter by September 30, 2006. In response to this mandate, manufacturers have begun to offer reformulated oral nasal decongestants that eliminate pseudoephedrine and rely instead on phenylephrine, which permits them to be sold over-the-counter without any restrictions.

However, in a peer-reviewed letter to the editor recently published in the Journal of Allergy and Clinical Immunology, two University of Florida researchers concluded that there is virtually no evidence to show that phenylephrine oral nasal decongestants at the FDA-sanctioned dose of 10 mg are effective.

A copy of Rep. Waxman's letter to FDA is online at www.democrats.reform.house.gov.