Reese, Cicely

From:

Sent: Thursday, December 01, 2005 1:05 PM

To: Reese, Cicely; Dockets, FDA

Cc: fourmasts@earthlink.com

Subject: drug application (NDA) 21-514--Disapprove

FDA Agenda:
The committee will discuss new drug application (NDA) 21-514, proposed trade name METHYPATCH (Methylphenidate) Tdp, (Methylphenidate Transdermal System), Noven Pharmaceuticals, proposed indication for the treatment of attention deficit hyperactivity disorder (ADHD).

Dear Cicely Reese:

Please note that I strongly disapprove of this drug and the patch. There are many reasons to disapprove of the drug, but for this instance, I will address the patch.

If approved, this patch will be put on children who will take it off and will likely apply it to another's skin. There is no way to monitor the safety of such a removable product.

I took care of developmentally disabled/dual-diagnosed children for 20 years. You cannot predict nor monitor their every waking moments, as with any child, let alone explain to them the importance of patch ownership.

As for adults with developmental disabilities, they too fall prey, in the same category. What is to say that another child or adult might take off the patch and use it for their own recreation?

This is way too risky. Think of the consequences if it was accidentally applied to a new born infant, or a fragile infant or and elderly invalid.

Please say NO to this drug and it's potential patch form.

Most Respectfully,
Debra L. Daniel