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September 28, 2000

Via Fax and Overnight Courier

Daniel Kerovich
Food and Drug Administration
OTC Drug Product Division
HFD 560
Room S-240
9201 Corporate Blvd.
Rockville, MD 20850

**Re: Citizen Petition For Nicotine Product Pregnancy Warning
Docket #00P-1432/CP1**

Dear Dan:

Pursuant to your request, please find enclosed the journal article, Drugs of Abuse and Placental Transport, which is listed as Item 10 on the References of Citizen's Petition provided to your office today. Please enclose this article with the others when you submit the references to the Docket's Management Office. If I can be of any further assistance, please feel free to contact me. Thank you.

Yours very truly,



Eric S. Somers

enc.

00P-1432

SUP1

LEXINGTON LAW GROUP
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September 27, 2000

Via Overnight Courier

Daniel Kerovich
Food and Drug Administration
OTC Drug Product Division
HFD 560
Room S-240
9201 Corporate Blvd.
Rockville, MD 20850

5728 00 OCT -4 P2:31

**Re: Citizen Petition For Nicotine Product Pregnancy Warning
Docket #00P-1432/CP1**

Dear Dan:

Pursuant to your request, please find enclosed two sets of all of the references cited in the above-referenced Citizen's Petition. Please note that item 10 on the list of references is not included. We will forward that reference to you tomorrow. Once you have a full set of references, please forward one set of the references to the Docket's Management Branch and request that they confirm the filing of this information with me. Your cooperation is appreciated. If you need any further information or have any other questions concerning this matter, please feel free to contact me.

Yours very truly,



Eric S. Somers

enc.

00P-1432

SUP 1

References to Citizen Petition

1. Levin, E.D. and Slotkin, T.A., Developmental Neurotoxicity of Nicotine, in W. Slikker and L.W. Chang (Eds.), Handbook of Developmental Neurotoxicology, pp. 587-615, Academic Press, San Diego, 1998
2. Slotkin, T.A., Cocaine Exposure: Which One Is Worse?, *J. Pharmacol. Exp. Ther.* 285 (1998) 931-945
3. Slotkin, T.A., Developmental Cholinotoxicants: Nicotine and Chlorpyrifos, *Environm. Hlth. Perspect.* 107 (1999) Suppl. 1, 71-80
4. Roy, T.S. and Sabherwal, U., Effects of Prenatal Nicotine Exposure on the Morphogenesis of Somatosensory Cortex, *Neurotoxicol. Teratol.* 16 (1994) 411-421
5. Roy, T.S. and Sabherwal, U., Effects of Gestational Nicotine Exposure on Hippocampal Morphology, *Neurotoxicol. Teratol.* 20 (1998) 465-473.
6. Milerad, J. and Sundell, H., Nicotine Exposure and the Risk of SIDS, *Acta Pædiat. Suppl.* 389 (1993) 70-72
7. Hafstrom, O., Milerad, J., Asokan, N., Poole, S.D. and Sundell, H.W., Nicotine Delays Arousal During Hypoxemia in Lambs, *Pediatr. Res.* 47 (2000) 646-652
8. Milerad, J., Larsson, H., Lin, J. and Sundell, H.W., Nicotine Attenuates the Ventilatory Response to Hypoxia in the Developing Lamb, *Pediatr. Res.* 37 (1995) 652-660.
9. Schuller, H.M., Jull, B.A., Sheppard, B.J. and Plummer, H.K., Interaction of Tobacco-Specific Toxicants with the Neuronal or, Nicotinic Acetylcholine Receptor and its Associated Mitogenic Signal Transduction Pathway: Potential Role in Lung Carcinogenesis and Pediatric Lung Disorders, *Eur. J. Pharmacol.* 393 (2000) 265-277.
10. Ganapathy, V., Prasad, P.D., Ganapathy, M.E. and Leibach, F.H., Drugs of Abuse and Placental Transport, *Adv. Drug Deliv. Rev.* 38 (1999) 99-110.