



National Specified List of Susceptible Products

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On February 20, 2004, the National Association of Boards of Pharmacy[®] (NABP[®]) released the updated Model Rules for the Licensure of Wholesale Distributors. The updated Model Rules, part of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*, were provided to assist state boards of pharmacy in maintaining the integrity of the United States medication distribution system through the regulation of wholesale distributors. The updated Model Rules are the result of a concerted effort between NABP and other representatives from pharmacy, the Food and Drug Administration (FDA), the Drug Enforcement Agency (DEA), state regulatory authorities, and the wholesale distributor industry to protect the public from the ill effects of counterfeit drugs and devices.

In addition to stricter licensing requirements such as criminal background checks and due diligence procedures prior to wholesale distribution transactions, the Model Rules mandate specific pedigree requirements for products that are particularly prone to adulteration, counterfeiting, or diversion. These products, as defined in the updated Model Rules, are designated on the “National Specified List of Susceptible Products.” In attempts to reduce redundancy and confusion as states update and adopt regulations, it is highly suggested that states adopt the NABP “National Specified List of Susceptible Products.”

The NABP “National Specified List of Susceptible Products”, originally released on February 27, 2004, was adapted from the Florida Statewide Pharmaceutical Services and Drug Wholesaler Advisory Council (Florida Department of Health). In mid 2004, NABP appointed the National Drug Advisory Coalition (NDAC). The NDAC was commissioned by NABP to develop criteria for determining which prescription drugs should be included on NABP’s “National Specified List of Susceptible Products” because of counterfeiting or susceptibility to counterfeiting. The NDAC was also charged with evaluating and revising NABP’s “National Specified List of Susceptible Products” on at least an annual basis. In this capacity, the NDAC will continue to serve as an advisory resource to the NABP Executive Committee, which will review the recommendations of the NDAC. On December 28, 2004, the revision criteria for NABP’s “National Specified List of Susceptible Products” were released along with this List.

The NDAC, appointed by the NABP Executive Committee, consisted of representation from the state boards of pharmacy, American Medical Association, American Society of Health-System Pharmacists, Healthcare Distribution Management Association, National Association of Chain Drug Stores, Pharmaceutical Distributors Association, Pharmaceutical Research and Manufacturers of America, and United States Pharmacopeia. Ex-officio members, who served as resources for the NDAC, included Food and Drug Administration, an independent counterfeit expert, and representation from the wholesale distribution and pharmaceutical manufacturing industries.

The following page contains the 32 drugs currently included on the “National Specified List of Susceptible Products.” Newly added to the List is Viagra[®], which was formally recommended by the NDAC and subsequently approved by the NABP Executive Committee.

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The National Association of Boards of Pharmacy Model Rules for the Licensure of Wholesale Distributors defines the “National Specified List of Susceptible Products” as a specific list of drugs or devices to be designated by the state, or a third party approved by the state, determined to be susceptible to adulteration, counterfeiting, or diversion and posing the potential for a greater public health risk.

1. Combivir[®] (lamivudine/zidovudine)
2. Crixivan[®] (indinavir)
3. Diflucan[®] (fluconazole)
4. Epivir[®] (lamivudine)
5. Epogen[®] (epoetin alfa)
6. Gamimune[®] (globulin, immune)
7. Gammagard[®] (globulin, immune)
8. Immune globulin
9. Lamisil[®] (terbinafine)
10. Lipitor[®] (atorvastatin)
11. Lupron[®] (leuprolide)
12. Neupogen[®] (filgrastim)
13. Nutropin AQ[®] (somatropin, E-coli derived)
14. Panglobulin[®] (globulin, immune)
15. Procrit[®] (epoetin alfa)
16. Retrovir[®] (zidovudine)
17. Risperdal[®] (risperidone)
18. Rocephin[®] (ceftriaxone)
19. Serostim[®] (somatropin, mammalian derived)
20. Sustiva[®] (efavirenz)
21. Trizivir[®] (abacavir/lamivudine/zidovudine)
22. Venoglobulin[®] (globulin, immune)
23. Viagra[®] (sildenafil)
24. Videx[®] (didanosine)
25. Viracept[®] (nelfinavir)
26. Viramune[®] (nevirapine)
27. Zeret[®] (stavudine)
28. Ziagen[®] (abacavir)
29. Zocor[®] (simvastatin)
30. Zofran[®] (ondansetron)
31. Zoladex[®] (goserelin)
32. Zyprexa[®] (olanzapine)