DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NOV 27 2001 150 '01 DEC -3 A9:24

The Honorable Rosa L. DeLauro
House of Representatives
Washington, D.C. 20515-0703

Dear Ms. DeLauro:

Thank you for your recent letter to the Food and Drug Administration (FDA or the Agency), regarding the shortage of the tetanus and diphtheria toxoids adsorbed vaccine and other drugs that are in short supply.

Please be assured that the FDA takes very seriously the concerns addressed in your letter. FDA does work closely with manufacturers in situations where their products are in short supply. In some instances, FDA has had discussions with other potential manufacturers of vaccines to urge them to seek licensure for their vaccines in the United States. Additionally, FDA is able to take other steps if necessary, such as expediting lot release of the product. Unfortunately, FDA can not force a manufacturer to continue manufacturing a product if the company chooses to discontinue the product.

Tetanus and diphtheria toxoids absorbed (Td) vaccine is indicated for active immunization against tetanus and diphtheria in adults and children seven years of age and older and recommended for booster use every ten years. The Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices recommends the use of the combined toxoids vaccine, such as the Td vaccine, rather than single component vaccines for both primary and booster injections, including active tetanus immunization in wound management.

The incidence of tetanus in the United States has dropped dramatically with the routine use of tetanus toxoid vaccines. During a situation of limited vaccine supply, the designated priority uses of the Td vaccine is for wound management at trauma centers and for vaccination of travelers to areas of the world with a high incidence of diphtheria.

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The supply of any vaccine is dependent upon the manufacturing capacity of the pharmaceutical companies and their interest in the sale of the vaccine. In early 2000, there were four licensed manufacturers of Td vaccine in the U.S. In October 2000, the Centers for Disease Control and Prevention reported a shortage of Td vaccine. In the winter of 2000, two of these manufacturers stopped producing and marketing the Td vaccine for business reasons. At present, Aventis-Pasteur is essentially the sole domestic manufacturer of Td vaccine. The Td vaccine is also manufactured by the Massachusetts Public Health Laboratories, primarily for use within the State of Massachusetts.

The Agency published a proposed rule in the Federal Register, November 7, 2000, which would implement provisions of the FDA Modernization Act by requiring an applicant who is the sole manufacturer of FDA regulated drug products to notify FDA at least six months before discontinuing manufacture of the drug product. By terms of the statute, the requirements of section 506C of the Act are limited to products that we have approved under the authority of section 505(b) or (j) of the Act. To implement this limitation, products we have approved under authority of section 351 of the Public Health Service Act (42 U.S.C. 262) would not be covered by this regulation. Therefore, a product like Td vaccine would not be covered under this rule. Enclosed is a copy of the notice requesting written comments. As David Doleski, of my staff, informed Mr. Mike Skonieczny, of your staff, we are forwarding this letter to FDA's docket for comments on the rule.

The Agency continues to work with the manufacturers of Td vaccines to help ensure the production of safe and efficacious vaccines.

Thank you for contacting us concerning this matter. If you have further questions, please let us know.

Sincerely,

Karen G. Meister
for

Melinda K. Plaisier
Associate Commissioner
for Legislation

Enclosure: November 7, 2000 Federal Register

cc: Dockets Management Branch, HFA-305
Docket #00N-1545

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Melinda K. Plaisier
Associate Commissioner for Legislation
Food and Drug Administration
5600 Fisher's Lane
Room 15-55
Rockville, MD 20857

Dear Ms. Plaisier:

It has come to my attention that there currently is a shortage of the tetanus diptheria vaccine. In addition, according to the FDA website, there are a variety of other drugs that also are in short supply.

While I understand FDA cannot force a manufacturer to produce a particular drug or vaccine, there is more we can do to ensure the availability of these important medicines. I would be interested to know how the FDA currently responds to drug and vaccine shortages. Is it mandatory for manufacturers to notify the FDA when they decide to stop manufacturing? What steps does the agency take to alleviate drug and vaccine shortages? Further, I would be interested in hearing any options you might suggest to further address this pressing public health issue.

Thank you for your prompt attention to this matter.

Sincerely,

Rosa L. DeLauro

ROSA L. DeLAURO
Member of Congress

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