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Reintroduction of Discontinued TB Drugs to Combat Epidemic

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Mary Pendergast, senior advisor to the commissioner of the Food and Drug Administration (FDA), reported at the recent World Congress on Tuberculosis in Bethesda, Maryland, that the FDA is concerned with the need for more effective drugs for treating tuberculosis because many of the existing antituberculosis drugs are either unavailable or in insufficient supply. She explained that the FDA is currently tracking down sources for existing antituberculosis drugs throughout the world, as well as urging United States drug manufacturers to keep antituberculosis drugs on the market, bring back discontinued drugs, and seek approval for new ones. The FDA is also planning to expedite the review of antituberculosis drugs, biologics, and devices.

Emergency supplies of streptomycin sulfate are being distributed through the Centers for Disease Control and Prevention (CDC) as an investigational drug until drug production can resume in the United States. Two generic drugs were approved last year for tuberculosis treatment, a form of amikacin and pyrazinamide. Additionally, the only injectable form of isoniazid, Nydrazid, has just been reintroduced at the request of the FDA and CDC. It will be useful for patients who are unable to take pills.

The FDA's willingness to accept foreign data for approval of drugs from outside the United States is evidenced by the drug Rifater. This agent is a combination of rifampin, isoniazid, and pyrazinamide and would make compliance with therapy much easier.