FDA Declines Serostim Approval for Lipo

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The Food and Drug Administration (FDA) declined this week to approve Serostim for the treatment of HIV-associated adipose redistribution syndrome (HARS)—the accumulation of fat associated with lipodystrophy. The drug, which has been in use since 1996 to treat AIDS-related wasting syndrome, may not be marketed for lipo. A spokesperson from Serostim-maker EMD Serono said that the company “remains committed to continuing our discussions with the FDA to obtain approval of Serostim for the treatment of HARS.” The FDA is expected to explain its decision next week.

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