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Tufts Center for the Study of Drug Development

Impact REPORT

ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

EMEA meets performance goals, but lags U.S. FDA in drug approvals

EMEA-FDA goal to offer parallel scientific advice likely to aid developers

- Mean approval times for 71 new medicinal products approved in the European Union (EU) by the European Medicines Agency (EMEA) through its centralized procedure and in the United States by the Food and Drug Administration (FDA) during 2000-05 were nearly identical (15.8 months vs. 15.7 months).
- However, the FDA approved a greater number of products (47) faster than the EMEA.
- Of the 71 products authorized by both agencies, 52 were approved first in the U.S., an average of 11.8 months before receiving EU approval.
- Products with exceptional circumstance designation in the EU and accelerated approval status in the U.S. had faster approval times than products lacking these designations.
- Medicinal products with an orphan designation had approval times similar to all products: an average of 16.8 months for the EMEA and 15.5 months by the FDA.