



FDA ADCOM Meeting Analytics in Cortellis


These analytics help you quickly pinpoint the Cortellis FDA Advisory Committee Meeting Bulletins for products similar to yours, making it easier to prepare to go before an advisory committee with your products. Filter by date, type of product, committee, indication and more.



Side by Side Viewer



FDA Drugs and Biologics Warning and Untitled Letters



FDA Drugs and Biologics Advisory Committee Meetings

- Access the FDA Analytics at the bottom of the Regulatory Home Page and **select FDA Drugs and Biologics Advisory Committee Meetings**.
- The Analytic opens in a new tab. The **Overview** section provides information about the analytic's scope, terminologies and rules.
- Click the **heading of interest** (e.g. Activity)

Click pies or bars in the charts to view corresponding bulletins in Details section below

Click buttons to change view by category

Select headings to open each report

Click hyperlinks to go to AdComm Bulletins or Approval Package reports

Hide or reset filters

Dynamic filters allow you to pinpoint bulletins by date, Advisory Committee, and more

Details section breaks down the specifics of each bulletin that matches your filtering

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Example: You are going before ODAC soon with a priority review oncology product and want to find ADCOMM bulletins for those products that received a Yes vote at committee and then later received an approval letter.

Overview

Activity

Voting Decisions

1.Select Voting Decisions report

Reset Filters

Filters

Search

Filters on this visual

% is (All)

Approval Header is (All)

Committee is (All)

Meetings is (All)

Filters on all pages

AdComm IDRAC Nu... is (All)

AdComm Date is (All)

Committee Name is Oncologic Drugs Advisory Committee

Application Type is (All)

Review Type is Priority review

Filter type

Basic filtering

Search

☒ Select all

312

☐ (Blank)

36

☐ Not available

36

☒ Priority review

3

☐ Standard review

3

History of the AC Votes

Votes by Committee

Votes by Therapeutic Area

Approval Header Committee	Equal Meetings	%	No Meetings	%
Oncologic Drugs Advisory Committee	2	6.06%	9	27.27%

4.Click the Yes section of the chart (green) to view the corresponding ADCOMM Bulletins in the Details table

5.Click the three dots to display all table details or export data to Excel

3.Limit Review Type filter to Priority

2.Limit Committee Name filter to Oncologic Drugs Advisory Committee (ODAC)

27 (71.1%)

9 (23.7%)

2 (5.3%)

● Yes ● No ● Equal

Details

AdComm Bulletin IDRAC Number	Approval Package IDRAC Number	AdComm Date	Committee Name	Application Type	Application Number	Product Name	Active Ingredient	Company	FDA Question
371974	375986	October 4, 2023	Oncologic Drugs Advisory Committee	NDA	215500	EFLORNITHINE	eflornithine	US WorldMeds	Has the sponsor provided sufficient evidence to conclude that DFMO improves EFS in patients with HRNB?
371974	375986	October 4, 2023	Oncologic Drugs Advisory Committee	NDA	215500	EFLORNITHINE	eflornithine	US WorldMeds	Has the sponsor provided sufficient evidence to conclude that DFMO improves EFS in patients with HRNB?
353096	283678	September 23, 2022	Oncologic Drugs Advisory Committee	NDA	211155	COPIKTRA	duvelisib	Secura Bio Inc.	Given the potential detriment in OS, duvelisib

6. Click the hyperlinks to open the AdComm Bulletins or Approval Packages directly from the Details section.

Regulatory Intelligence Report

Deep dive analysis from Cortellis

Clarivate

Oncologic Drugs Advisory Committee (AdComm Bulletin): Cautious Support for Eflornithine to Prevent Pediatric Neuroblastoma Relapse, 04-Oct-2023

1. Meeting Information

Oncologic Drugs Advisory Committee (AdComm Bulletin): Eflornithine From US WorldMeds to Prevent Relapse in Pediatric Neuroblastoma (NDA 215500), 04-Oct-2023

AdComm Profiles and Voting Histories—Drugs/Biologics (IDRAC 175864)

Subject:

New drug application (NDA) 215500: eflornithine tablets (DFMO), submitted by USWM, LLC (doing business as US WorldMeds), for reduction of the risk of relapse in pediatric patients with high-risk neuroblastoma (HRNB) who have completed multiagent, multimodality therapy.

Announced in the Federal Register

August 16, 2023 (IDRAC 369690)

(Volume 88, Number 157)

2. Decision/Voting

The Oncologic Drugs Advisory Committee (ODAC) voted in the majority in favor of the evidence for eflornithine (DFMO), submitted by USWM, LLC (doing business as US WorldMeds), in support of reducing the risk of relapse in pediatric patients with high-risk neuroblastoma (HRNB) who have completed multiagent, multimodality therapy. While no consensus was reached regarding topics such as requiring the sponsor to conduct a randomized controlled trial (RCT) or the strength of the DFMO treatment effect, ODAC members generally agreed that results from an externally controlled trial (ECT) and additional clinical and nonclinical evidence demonstrated some efficacy in pediatric subjects, despite the presence of potential confounding variables (e.g., patient education level, access to healthcare).

FDA Question(s) to the Committee	Yes	No	Comments
Has the sponsor provided sufficient evidence to conclude that DFMO improves EFS in patients with HRNB?	14	6	

NOTE: The FDA is not obligated to follow the voting recommendation of the advisory committee, but it

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