Regulatory Factsheet

Scientific advice US-FDA

US Food and Drug Administration

The FDA has four meeting types, type A (help a stalled product development program), type B (pre-IND meeting, pre- NDA/BLA meeting, meeting to discuss overall development for products granted breakthrough therapy designation), end of phase type B (certain end of phase 1 meetings, end of phase 2 and pre phase 3 meetings), and type C (any meeting regarding development and review of a product that isn't any of the other types).

To submit a request to the FDA a simple form or letter stating the meeting type being requested, suggested date and times for the meeting, a list of proposed questions grouped by FDA discipline, proposed indication, meeting objectives etc. The meeting request must also include the proposed meeting format, the date the meeting background package will be sent by the requester, a list of planned attendees from the requester's organisation and a list of requested FDA attendees and/or their discipline representatives.

Scientific advice meetings allow the FDA to see the scope of the request and allows the FDA to ensure sufficient expertise is available. Although the advice given is not legally binding, not following it will require justification in subsequent licensing applications.

PARALLEL US/EU Advice

Used to support global development of important breakthrough drugs or for important safety issues (Oncology, Vaccines, Orphan drugs, Advanced therapies, paediatric use). Parallel advice should ideally be timed to coincide with End of phase 2 or pre-IND meeting with FDA.

A synchronised request submission allows for increased communication and exchange of views (exchange of documents, discussion meeting by videoconferencing).

However, each Agency provides its own advice, there is no combined output. FDA and EMA may not agree on all issues.

At a glance

Agency

FDA U.S. FOOD & DRUG ADMINISTRATION

Criteria

- Form/letter detailing meeting objectives with draft questions
- Briefing Package to provide background information and company's position (rationale for proposal)
- Annexes should include key information (protocol synopses, Investigators' Brochure)

Timings

- Can be done at any time over the course of development

Agency fees

- FDA does not have any fees for scientific advice

FDA Timelines:

Meeting Type	FDA Response to Request	FDA Receipt of Meeting Package	FDA Preliminary Responses to Requester (if applicable)	Requester Response to FDA Preliminary Responses (if applicable)	FDA Scheduled Meeting Date (days from receipt of request)	FDA Meeting Minutes to Requester (if applicable)
A	14 days	With meeting request	No later than 2 days before meeting	--	Within 30 days	30 days after meeting
B	21 days	No later than 30 days before meeting	No later than 2 days before meeting	--	Within 60 days	30 days after meeting
B (EOP)*	14 days	No later than 50 days before meeting	No later than 5 days before meeting	No later than 3 days after receipt of preliminary responses	Within 70 days	30 days after meeting
C	21 days	No later than 47 days before meeting	No later than 5 days before meeting	No later than 3 days after receipt of preliminary responses	Within 75 days	30 days after meeting