MINTZ

Pharmaceutical
Branding & Advertising

Complex Mission-Critical Terrain

Failure to secure the requisite approvals for drug names and launch campaigns can disrupt a timely commercial launch. Companies must navigate an intricate dual-track legal process across trademark agencies (e.g., US Patent & Trademark Office) and regulatory agencies (e.g., US Food & Drug Administration) in order to bring a branded drug to market. Our highly experienced attorneys guide clients through each step of the process to help them avoid pitfalls and successfully commercialize their drugs or biologics.

// AREAS OF FOCUS

- Clinical trial branding
- Drug name trademark clearance and filings
- FDA proprietary name approvals
- Global brand strategy counseling
- International Nonproprietary Name & US Adopted Name approvals
- Pharmaceutical trademark policing & enforcement
- Brand licensing & marketing agreements
- Advertising & promotional materials review
- FDA/FTC enforcement & warning letters
- FDA submissions & strategic communications

// DON'T JEOPARDIZE YOUR COMMERCIAL LAUNCH

From clinical trial brands and drug names to launch campaigns, life sciences clients face unique branding and advertising issues — many of which directly impact their ability to bring products to market. In particular, the multitrack drug name approval processes in key countries are a constantly evolving and complex maze of crisscrossing requirements, timelines, priorities, and procedures (with no reciprocity). Success requires early planning and sophisticated strategies coordinated across multiple countries and government agencies.

Our pharmaceutical branding and advertising team has guided many clients to successful commercialization. Whether you are just starting the naming process for a generic or branded drug, facing agency rejections, disputing with competitors, or preparing promotional campaigns, make sure you receive critical guidance in order to launch, enhance, and protect your pharmaceutical product in the marketplace.

MINTZ

Start the **drug naming process** by the earlier of:
(i) 2 years before FDA submission or **(ii)** 3 years before commercialization.

POST PHASE I

- Develop & search clinical trial brands
- Obtain generic names from WHO and USAN

EARLY PHASE II

- Creative naming process
- Market & safety research process
- Conduct trademark clearance searches

MID PHASE II

- File US trademark applications
- File foreign trademark applications
- Register domains and social media

POST PHASE II

- Submit top two names to FDA for first conditional approval
- Submit top two names to EMA for approval

FDA SUBMISSION

- Submit top two names to FDA for second conditional approval
- Develop & protect product logo
- Develop & protect campaign brand assets

APPROVAL

- FDA final drug name review 90 days before PDUFA
- Final drug name approved with label

// TEAM

Mintz's pharmaceutical branding and advertising attorneys combine deep legal capabilities and industry knowledge to advise on immediate legal issues as well as long-term business objectives. They are an integral part of the firm's nationally ranked cross-disciplinary team of 150+ attorneys and professionals focused on life sciences clients.

KAREN K. WON
Member / New York
KWon@mintz.com
212.692.6704

JOANNE S. HAWANA
Member / Washington, DC
JSHawana@mintz.com
202.434.7349