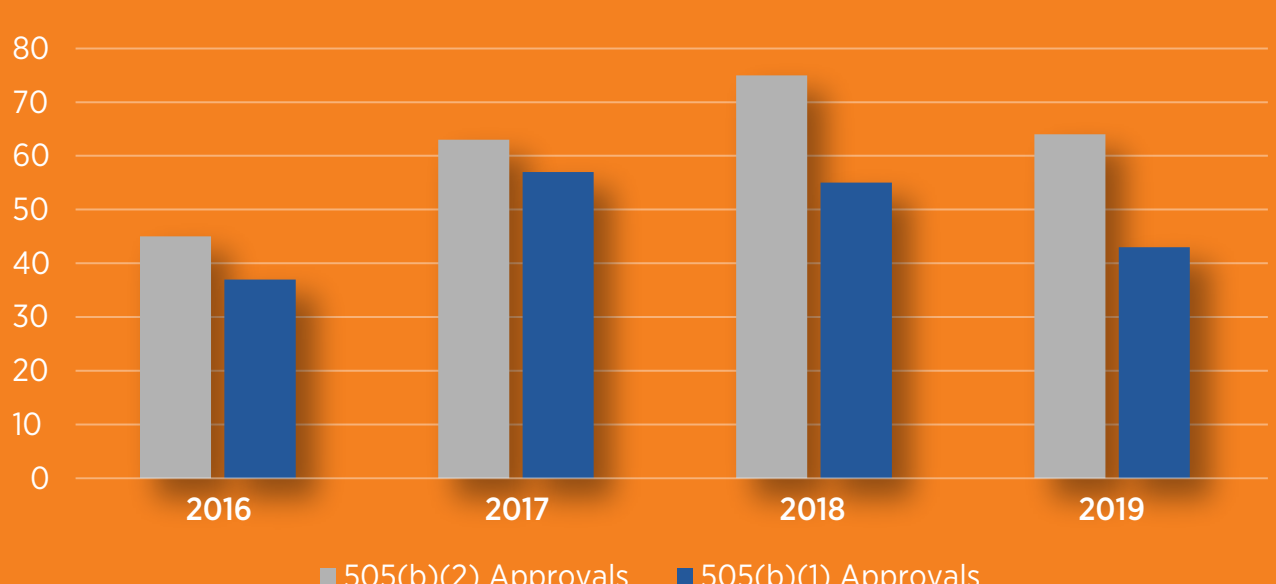
2019 505(b)(2) NDA Approvals

Sponsor Insights

From which FDA division approved them, to who brought them to market, take a deeper dive into the 64 505(b)(2) NDA approvals of 2019.

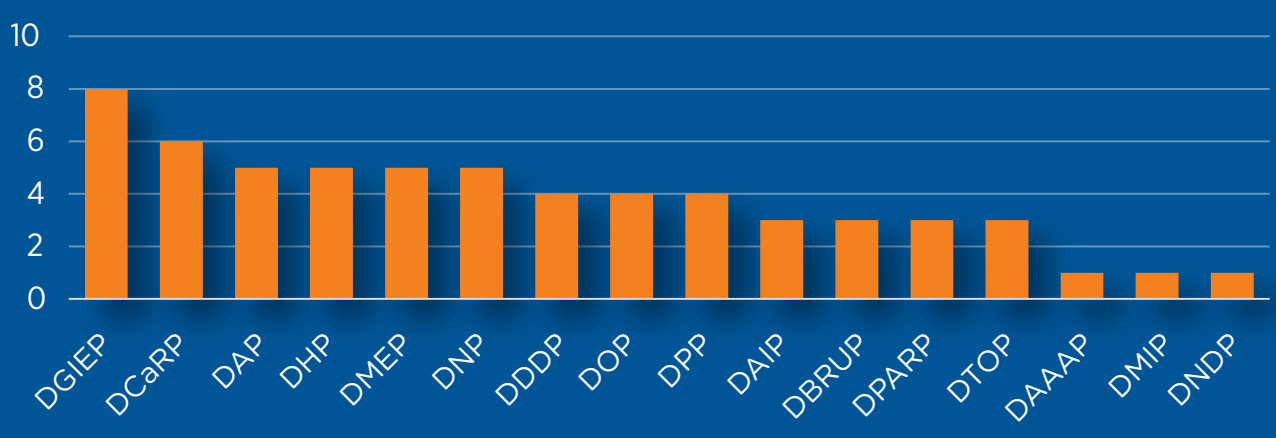
How do 505(b)(2) approvals compare to 505(b)(1) approvals?

The 505(b)(2) pathway plays an important role in addressing unmet patient needs, consistently bringing to market more therapies than the 505(b)(1) pathway, typically with less cost, time, and risk.



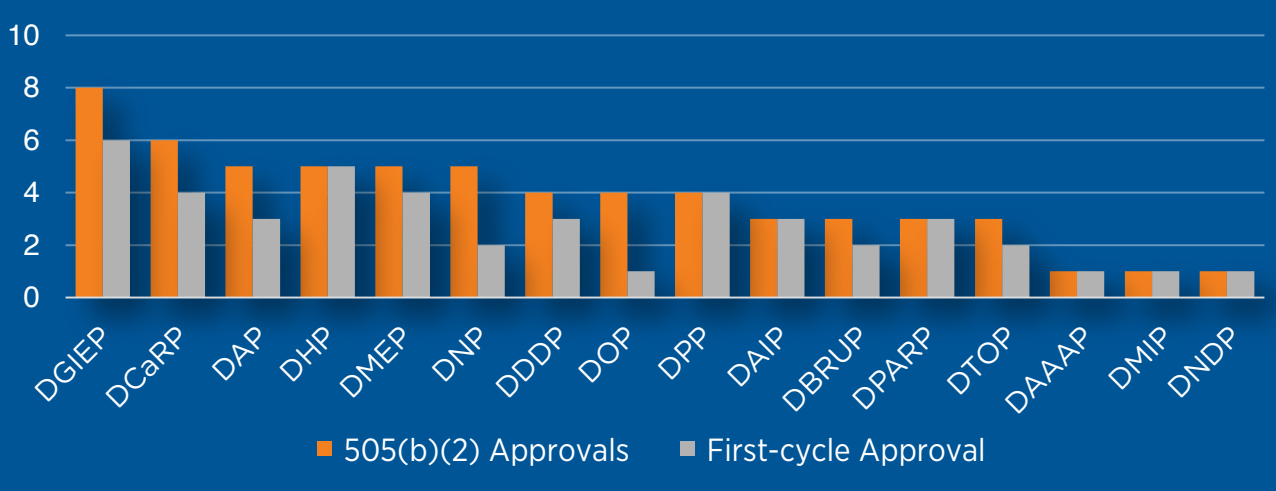
Which FDA divisions approved 505(b)(2) submissions?

The FDA's Division of Gastroenterology and Inborn Errors Products had the most 505(b)(2) approvals, with indications ranging from nausea and vomiting for cancer patients, to Chron's disease, parenteral nutrition, and phosphorous deficiency.



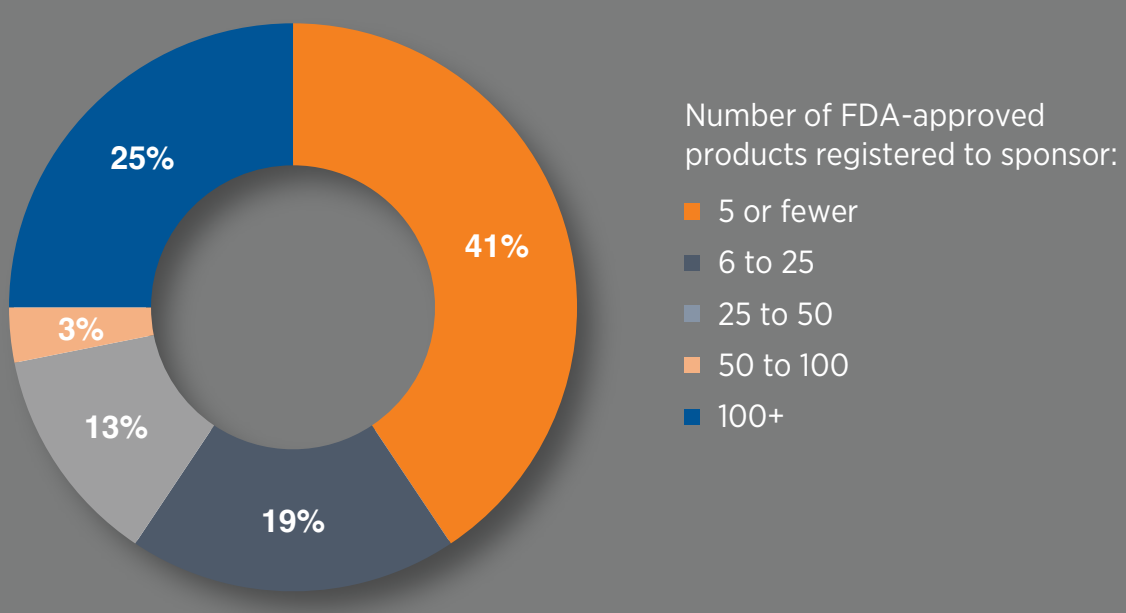
How many 505(b)(2) submissions were approved on the first review cycle?

47 of the 64 total 505(b)(2) NDAs (73%) were first-cycle approvals, meaning no complete response letter was issued requiring re-submission with additional information.



Who brought to market the 505(b)(2) products approved in 2019?

41% of 505(b)(2) approvals were submitted by sponsors with five or fewer FDA-approved products[1]. For seven sponsors, the 505(b)(2) product approval was their only FDA-approved product.



How many 505(b)(2) products have been licensed to another company?

To date, four 505(b)(2) products approved in 2019 have been licensed to another company[2]

1. **Biorphen** (phenylephrine hydrochloride), submitted by Sintetica, was licensed to Eton Pharmaceuticals
2. **Bonsity** (teriparatide), submitted by Pfenex, was licensed to Alvogen, accompanied by a $2.5 million milestone payment
3. **Gloperba** (colchicine), submitted by Romeg Therapeutics, was licensed to Avion Pharmaceuticals
4. **Myxredlin** (insulin human), submitted by Celerity Pharmaceuticals, was transferred to its medical products partner, Baxter International

[1] Number includes currently marketed and discounted products in the U.S. Based on Orange Book data and current as of 2/8/2020
[2] Based on Orange Book data as of 2/8/2020.
Unless otherwise noted, all data has been prepared from Premier Consulting's proprietary 505(b)(2) database