thus, constitute untrue statements of material fact.

In the August 14, 1990, amendment to its then pending supplement, KV also selectively reported only a passing result for a 12-month stability test for lot L2071 (400 mg) for methylparaben, an inactive ingredient, although KV's records showed an initial unreported result in which the lot failed to meet the firm's specifications approved in the AADA for methylparaben.

In the August 14, 1990, amendment to its then pending supplement, KV falsely reported that lot L2072 (200 mg) passed a 6-month stability test for methylparaben. However, KV's records for the same time and storage conditions showed that L2072 failed to meet the firm's specifications as approved in the AADA.

FDA's inspection also established that KV made untrue statements in certain annual reports by submitting false stability study results and by omitting failing stability results for EES 200 mg and 400 mg. In KV's April 30, 1991, annual report for its 200 mg EES product, the firm falsely stated that lot L2510 passed an erythromycin assay at 3 months. However, records from the outside contract laboratory that conducted the 3-month assay show that the erythromycin assay results for lot L2510 were below the U.S.P. specifications.

In KV's September 26, 1991, annual report for EES 400 mg, the firm falsely reported that the assay of the active ingredient in lot L2071 passed stability testing at 18 months. Records at the firm, however, showed that lot L2071 failed testing at 18 months because the results were below U.S.P. specifications.

Records from KV show that EES lot L1791 (200 mg) failed assays for erythromycin and for an inactive ingredient at 18 months. KV, however, did not report these failures in its April 30, 1991, annual report as required under 21 CFR 314.81. On April 28, 1992, KV recalled both strengths of EES because of recurrent stability problems. Only after this recall, in the firm's June 2, 1992, annual report, did KV report the stability test failures of EES lot L1791.

The stability failures in 1990 and 1991 were capable of affecting FDA's continued approval of the AADA because they provide evidence directly relevant to the product's safety and effectiveness. KV's omission in the April 30, 1991, annual report of the available information about the 1990 and 1991 failures misrepresented the product's quality at that time and, therefore, the applications contain untrue statements of material fact.

2. ANDA 71–929, Disopyramide Phosphate Extended Release Capsules, 100 mg

FDA's inspections of KV revealed that the firm made untrue statements about the stability of its Disopyramide Phosphate Extended Release Capsules (100 mg) in its September 10, 1992, annual report, as explained below. Disopyramide Phosphate Extended Release Capsules must meet the specifications regarding strength, quality, and purity prescribed in the approved ANDA, as amended. The stability data submitted in the annual reports and discussed below are false and misleading and are material to the continued approval of the ANDA application.

First, KV reported that in December 1991, lot V1040 passed ANDA specifications for 18-month drug release testing at 1, 4, and 8-hour intervals. Records at the firm, however, showed that the six capsules tested by KV on December 11, 1991, failed the 4-hour test both individually and collectively. These failing data were lined through and the notation ''Inconsistent with history and retest'' was added. No other notation or explanation of KV's December 11, 1991, test results was recorded. KV did not report this failure in the September 10, 1992, annual record or record an explanation for omitting this failure from the annual report. Five days later, on December 16, 1991, KV tested another six capsules, which passed the 4-hour specifications. KV selectively reported only the average of the passing test results in the annual report, and the omission of failing data in the annual report was misleading.

KV also reported in the September 10, 1992, annual report that in April 1991, the 3-month drug release test for lot V1377 passed ANDA specifications at the 4-hour interval. Records at the firm, however, showed that on April 18, 1991, the aggregate average value of the six capsules tested was below drug release specifications for the 4-hour interval. Five of the six individual capsules were also below specifications at 4 hours. These failing data were not reported in the September 10, 1992, annual report.

Four months later, on August 18 and 19, 1991, KV reassayed the lot three times and selectively reported only the results from the first reassay. Furthermore, in the September 10, 1992, annual report, KV falsely reported that the drug release test result had been obtained at 3 months, but KV's records showed that it had been obtained at 7 months.

KV also reported in the September 10, 1992, annual report that lot V1497 passed both 4 and 8 hour, 12-month drug release tests in May 1992. KV's records, however, showed that a set of six capsules failed the 8 hour, 12-month ANDA drug release test on July 21, 1992. On August 3, 1992, a second set of six capsules passed both 4 and 8 hour drug release tests. However, these results were crossed out on the firm's stability data report form. A handwritten note next to these results reads ''Void. See recal using correct shell factor.'' On August 8, 1992, KV recalculated both the 4-hour and 8-hour drug release test results. The aggregate averages for both 4 hour and 8 hour tests passed specifications. However, two of the six capsules failed at 4 hours and two of the six capsules failed at 8 hours. The notation ''Recal'' is written beside this third set of data. KV selectively reported only the passing 4 and 8 hour aggregate average results in the September 1992, annual report.

3. ANDA 86–538, Nitroglycerin Extended Release Capsules, 2.5 mg

FDA's inspections of KV revealed that the firm made untrue statements in certain annual reports about the stability of its Nitroglycerin Extended Release Capsules. These untrue statements consisted of false reporting and selective reporting of stability data, including content uniformity data, which are material to the continued conditional approval of the application.

In its April 29, 1988, annual report, KV reported that on July 28, 1987, the content uniformity test data for lot V8715 were not available at 24 months. KV's records, however, included content uniformity test results for this lot, which showed that lot V8715 failed to meet U.S.P. specifications at 24 months. Although Nitroglycerin Extended Release Capsules is not listed in the U.S.P., the standard test for content uniformity of any product is described in the U.S.P., and KV's submissions stated that it met the U.S.P. test.

In its June 6, 1989, annual report, KV reported that the 12-month assay for nitroglycerin in lot V8648 tested within the ANDA specifications. KV's records, however, showed that an assay result was outside the ANDA assay limits. The passing result KV reported was an average of the failing result and two additional assays it performed.

In the June 6, 1989, annual report, KV reported that a nitroglycerin assay purportedly conducted at 9 months after lot V9527 was within ANDA specifications. KV's records, however, showed that the KV lab test result,