Safety Labeling Changes—Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act

OMB Control Number 0910–0734—Extension

Section 505(o)(4) of the FD&C Act (21 U.S.C. 355(o)(4)) authorizes FDA to require and, if necessary, order labeling changes if FDA becomes aware of new safety information that it believes should be included in the labeling of certain prescription drug and biological products approved under section 505 of the FD&C Act or section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262). Section 505(o)(4) of the FD&C Act applies to prescription drug products with an approved new drug application (NDA) under section 505(b) of the FD&C Act, biological products with an approved biologics license application under section 351 of the PHS Act, or prescription drug products with an approved abbreviated new drug application under section 505(j) of the FD&C Act if the reference listed drug with an approved NDA is not currently marketed. Section 505(o)(4) imposes time frames for application holders to submit, and FDA staff to review, such changes and gives FDA enforcement tools to bring about timely and appropriate labeling changes. To implement these provisions we developed the guidance entitled ''Guidance for Industry: Safety Labeling Changes—Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act,'' which provides instruction on: (1) A description of the types of safety labeling changes that ordinarily might be required; (2) how FDA plans to determine what constitutes new safety information; (3) the procedures involved in requiring safety labeling changes, and (4) enforcement of the requirements for safety labeling changes. The guidance is available on our website at *https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm250783.pdf.*

FDA requires safety labeling changes by sending a notification letter to the application holder. Under section 505(o)(4)(B) of the FD&C Act, the application holder must respond to FDA's notification by submitting a labeling supplement or notifying FDA that the applicant does not believe the labeling change is warranted and by submitting a statement detailing why the application holder does not believe a change is warranted (a rebuttal statement).

Based on our experience to date with safety labeling changes requirements under section 505(o)(4) of the FD&C Act, we estimate that approximately 36 application holders will elect to submit approximately 1 rebuttal statement each year and that each rebuttal statement will take approximately 6 hours to prepare.

In addition, the guidance explains that labeling prepared in response to a safety labeling change notification should be available on the application holder's website within 10 calendar days of approval. We estimate that approximately 351 application holders will post new labeling one time each year in response to a safety labeling change notification and that the posting of the labeling will take approximately 4 hours to prepare.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Rebuttal statement	36	1	36	6	216

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Type of submission	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Posting approved labeling on application holder's website	351	1	351	4	1,404

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We have adjusted our estimated annual number of respondents downward by 62 since the last OMB approval of the information collection. The decrease reflects that we have issued fewer safety labeling notifications, and thus fewer postings are required and fewer rebuttals are expected.

Dated: February 6, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–01918 Filed 2–11–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1721]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Investigational New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 14, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0014. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Investigational New Drug Application—21 CFR Part 312

OMB Control Number 0910–0014–Extension

This information collection supports FDA regulations in 21 CFR part 312 covering Investigational New Drugs. Part 312 implements provisions of section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) requiring FDA to issue regulations under which the clinical investigation of the safety and effectiveness of unapproved new drugs and biological products can be conducted.

FDA is charged with implementing statutory requirements that ensure drug products marketed in the United States are shown to be safe and effective, properly manufactured, and properly labeled for their intended uses. Section 505(a) of the FD&C Act provides that a new drug may not be introduced or delivered for introduction into interstate commerce in the United States unless FDA has previously approved a new drug application (NDA). FDA approves an NDA only if the sponsor of the application first demonstrates that the drug is safe and effective for the conditions prescribed, recommended, or suggested in the product's labeling. Proof must consist, in part, of adequate and well-controlled studies, including studies in humans, that are conducted by qualified experts.

The investigational new drug application (IND) regulations under part 312 establish reporting requirements that include an initial application as well as amendments to that application, reports on significant revisions of clinical investigation plans, and information on a drug's safety or effectiveness. In addition, the sponsor is required to give FDA an annual summary of the previous year's clinical experience. The regulations also include recordkeeping requirements pertaining to the disposition of drugs, records pertaining to individual case histories, and certain other documentation verifying the fulfillment of responsibilities by clinical investigators.

Submissions are reviewed by medical officers and other Agency scientific reviewers assigned responsibility for overseeing a specific study. The details and complexity of these requirements are dictated by the scientific procedures and human subject safeguards that must be followed in the clinical tests of investigational new drugs.

The IND information collection requirements provide the means by which FDA can monitor the clinical investigation of the safety and effectiveness of unapproved new drugs and biological products, including the following: (1) Monitor the safety of ongoing clinical investigations; (2) determine whether the clinical testing of a drug should be authorized; (3) ensure production of reliable data on the metabolism and pharmacological action of the drug in humans; (4) obtain timely information on adverse reactions to the drug; (5) obtain information on side effects associated with increasing doses; (6) obtain information on the drug's effectiveness; (7) ensure the design of well-controlled, scientifically valid studies; and (8) obtain other information pertinent to determining whether clinical testing should be continued and information related to the protection of human subjects. Without the information provided by industry as required under the IND regulations, FDA cannot authorize or monitor the clinical investigations that must be conducted before authorizing the sale and general use of new drugs. These reports enable FDA to monitor a study's progress, to ensure the safety of subjects, to ensure that a study will be conducted ethically, and to increase the likelihood that the sponsor will conduct studies that will be useful in determining whether the drug should be marketed and available for use in medical practice.

To assist respondents with certain reporting requirements under part 312, we have developed two forms: Form FDA 1571 entitled, ''Investigational New Drug Application (IND)'' and Form FDA 1572 entitled, ''Statement of Investigator.'' Anyone who intends to conduct a clinical investigation must submit Form FDA 1571 as instructed. The reporting elements include: (1) A cover sheet containing background information on the sponsor and investigator; (2) a table of contents; (3) an introductory statement and general investigational plan; (4) an investigator's brochure describing the drug substance; (5) a protocol for each planned study; (6) chemistry, manufacturing, and control information for each investigation; (7) pharmacology and toxicology information for each investigation; and (8) previous human experience with the investigational drug. Form FDA 1572 is executed and submitted by the IND sponsor before an investigator may participate in an investigation. It includes background information on the investigator as well as the investigation, and a general outline of the planned investigation and study protocol.

In the **Federal Register** of October 4, 2018 (83 FR 50102) FDA published a 60-day notice requesting public comment on the proposed collection of information. We received one comment. The comment did not pertain to the regulations or estimates provided in the 60-day notice requesting that OMB extend its approval for the information collection in these regulations. Rather, the comment discussed issues that pertained to Docket No. FDA–2010–D–0503 for the ''Guidance for Clinical Investigators, Sponsors, and Institutional Review Boards (IRBs): Investigational New Drug Applications (INDs)—Determining Whether Human Research Studies Can Be Conducted Without an IND.'' Accordingly, we have submitted the comment to Docket No. FDA–2010–D–0503.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN FOR HUMAN DRUGS (CDER) [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§ 312.2(e); Requests for FDA advice on the applicability of part 312 to a planned clinical investigation	400	1	400	24	9,600
§ 312.8; Requests to charge for an investigational drug	74	1.23	91	48	4,368
§ 312.10; Requests to waive a requirement in part 312	86	1.84	158	24	3,792

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN FOR HUMAN DRUGS (CDER) [1]—Continued

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§ 312.23(a) through (f); IND content and format (including Form FDA 1571)	2,187	1.7	3,718	1,600	5,948,800
§ 312.30(a) through (e); Protocol amendments	4,418	5.52	24,387	284	6,925,908
§ 312.31(b); Information amendments	6,691	3.32	22,214	100	2,221,400
§ 312.32(c) and (d); IND safety reports	867	15.78	13,681	32	437,792
§ 312.33(a) through (f); IND annual reports	3,376	2.86	9,655	360	3,475,800
§ 312.38(b) and (c); Notifications of withdrawal of an IND	930	1.61	1,497	28	41,916
§ 312.42; Sponsor requests that a clinical hold be removed, including sponsor submission of a complete response to the issues identified in the clinical hold order	198	1.38	273	284	77,532
§ 312.44(c) and (d); Sponsor responses to FDA when IND is terminated	12	1.16	14	16	224
§ 312.45(a) and (b); Sponsor requests for or responses to an inactive status determination of an IND by FDA	231	1.84	425	12	5,100
§ 312.47; Meetings, including "End-of-Phase 2" meetings and "Pre-NDA" meetings	122	1.51	184	160	29,440
§ 312.54(a); Sponsor submissions to FDA concerning investigations involving an exception from informed consent under § 50.24	15	2.4	36	48	1,728
§ 312.54(b); Sponsor notifications to FDA and others concerning an IRB determination that it cannot approve research because it does not meet the criteria in the exception from informed consent in § 50.24(a)	2	1	2	48	96
§ 312.56(b), (c), and (d); Sponsor notifications to FDA and others resulting from: (1) The sponsor's monitoring of all clinical investigations and determining that an investigator is not in compliance with the investigation agreements; (2) the sponsor's review and evaluation of the evidence relating to the safety and effectiveness of the investigational drug; and (3) the sponsor's determination that the investigational drug presents an unreasonable and significant risk to subjects	6,100	7	42,700	80	3,416,000
§ 312.58(a); Sponsor's submissions of clinical investigation records to FDA on request during FDA inspections	73	1	73	8	584
§ 312.70; During the disqualification process of a clinical investigator by FDA, the number of investigator responses or requests to FDA following FDA's notification to an investigator of its failure to comply with investigation requirements	4	1	4	40	160
§ 312.110(b)(4) and (b)(5); Written certifications and written statements submitted to FDA relating to the export of an investigational drug	11	26.28	289	75	21,675
§ 312.120(b); Submissions to FDA of "supporting information" related to the use of foreign clinical studies not conducted under an IND	1,414	8.62	12,189	32	390,048
§ 312.120(c); Waiver requests submitted to FDA related to the use of foreign clinical studies not conducted under an IND	35	2.34	82	24	1,968
§ 312.130; Requests for disclosable information in an IND and for investigations involving an exception from informed consent under § 50.24	3	1	3	8	24
§§ 312.310(b) and 312.305(b); Submissions related to expanded access and treatment of an individual patient	935	2.77	2,590	8	20,720
§ 312.310(d); Submissions related to emergency use of an investigational new drug	480	2.15	1,032	16	16,512
§§ 312.315(c) and 312.305(b); Submissions related to expanded access and treatment of an intermediate-size patient population	118	2.52	297	120	35,640
§ 312.320(b); Submissions related to a treatment IND or treatment protocol	10	12.9	129	300	38,700
Total					23,125,527

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR HUMAN DRUGS (CDER) [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
§ 312.52(a); Sponsor records for the transfer of obligations to a contract research organization	1,300	1	1,300	2	2,600
§ 312.57; Sponsor recordkeeping showing the receipt, shipment, or other disposition of the investigational drug and any financial interests	13,000	1	13,000	100	1,300,000
§ 312.62(a); Investigator recordkeeping of the disposition of drugs	13,000	1	13,000	40	520,000
§ 312.62(b); Investigator recordkeeping of case histories of individuals	13,000	1	13,000	40	520,000
§ 312.160(a)(3); Records pertaining to the shipment of drugs for investigational use in laboratory research animals or in vitro tests	547	1.43	782	* 0.50	391
§ 312.160(c); Shipper records of alternative disposition of unused drugs	547	1.43	782	* 0.50	391
Total					2,343,382

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
* 30 minutes.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN FOR HUMAN DRUGS (CDER) [1]

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
§ 312.53(c); Investigator reports submitted to the sponsor, including Form FDA 1572, curriculum vitae, clinical protocol, and financial disclosure	1,732	7.94	13,752	80	1,100,160
§ 312.55(a); Investigator brochures submitted by the sponsor to each investigator	995	4	3,980	48	191,040
§ 312.55(b); Sponsor reports to investigators on new observations, especially adverse reactions and safe use	995	4	3,980	48	191,040
§ 312.64; Investigator reports to the sponsor, including progress reports, safety reports, final reports, and financial disclosure reports	13,000	1	13,000	24	312,000
Total					1,794,240

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 4—ESTIMATED ANNUAL REPORTING BURDEN FOR BIOLOGICS (CBER) [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§ 312.2(e); Requests for FDA advice on the applicability of part 312 to a planned clinical investigation	217	1.18	256	24	6,144
§ 312.8; Requests to charge for an investigational drug	20	1.50	30	48	1,440
§ 312.10;Requests to waive a requirement in part 312	2	1	2	24	48
§ 312.23(a) through (f); IND content and format	335	1.35	452	1,600	723,200
§ 312.30(a) through (e); Protocol amendments	694	5.84	4,053	284	1,151,052
§ 312.31 (b); Information amendments	77	2.43	187	100	18,700
§ 312.32(c) and (d); IND Safety reports	161	8.83	1,422	32	45,504
§ 312.33(a) through (f); IND Annual reports	745	2.14	1,594	360	573,840
§ 312.38(b) and (c); Notifications of withdrawal of an IND	134	1.69	226	28	6,328
§ 312.42; Sponsor requests that a clinical hold be removed, including sponsor submission of a complete response to the issues identified in the clinical hold order	67	1.30	87	284	24,708
§ 312.44(c) and (d); Sponsor responses to FDA when IND is terminated	34	1.15	39	16	624
§ 312.45(a) and (b); Sponsor requests for or responses to an inactive status determination of an IND by FDA	55	1.38	76	12	912
§ 312.47; Meetings, including "End-of-Phase 2" meetings and "Pre-NDA" meetings	88	1.75	154	160	24,640
§ 312.53(c); Investigator reports submitted to the sponsor, including Form FDA 1572, curriculum vitae, clinical protocol, and financial disclosure	453	6.33	2,867	80	229,360

TABLE 4—ESTIMATED ANNUAL REPORTING BURDEN FOR BIOLOGICS (CBER) [1]—Continued

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§ 312.54(a); Sponsor submissions to FDA concerning investigations involving an exception from informed consent under § 50.24	1	1	1	48	48
§ 312.54(b); Sponsor notifications to FDA and others concerning an IRB determination that it cannot approve research because it does not meet the criteria in the exception from informed consent in § 50.24(a)	1	1	1	48	48
§ 312.55(a); Number of investigator brochures submitted by the sponsor to each investigator	239	1.91	456	48	21,888
§ 312.55(b); Number of sponsor reports to investigators on new observations, especially adverse reactions and safe use	243	4.95	1,203	48	57,744
§ 312.56(b), (c), and (d); Sponsor notifications to FDA and others resulting from: (1) The sponsor's monitoring of all clinical investigations and determining that an investigator is not in compliance with the investigation agreements; (2) the sponsor's review and evaluation of the evidence relating to the safety and effectiveness of the investigational drug; and (3) the sponsor's determination that the investigational drug presents an unreasonable and significant risk to subjects	108	2.21	239	80	19,120
§ 312.58(a); Number of sponsor's submissions of clinical investigation records to FDA on request during FDA inspections	7	1	7	8	56
§ 312.64; Number of investigator reports to the sponsor, including progress reports, safety reports, final reports, and financial disclosure reports	2,728	3.82	10,421	24	250,104
§ 312.70; During the disqualification process of a clinical investigator by FDA, the number of investigator responses or requests to FDA following FDA's notification to an investigator of its failure to comply with investigation requirements	5	1	5	40	200
§ 312.110(b)(4) and (b)(5); Number of written certifications and written statements submitted to FDA relating to the export of an investigational drug	18	1	18	75	1,350
§ 312.120(b); Number of submissions to FDA of "supporting information" related to the use of foreign clinical studies not conducted under an IND	280	9.82	2,750	32	88,000
§ 312.120(c); Number of waiver requests submitted to FDA related to the use of foreign clinical studies not conducted under an IND	7	2.29	16	24	384
§ 312.130; Number of requests for disclosable information in an IND and for investigations involving an exception from informed consent under § 50.24	350	1.34	469	8	3,752
§ 312.310(b) and 312.305(b); Number of submissions related to expanded access and treatment of an individual patient	78	1.08	84	8	672
§ 312.310(d);Number of submissions related to emergency use of an investigational new drug	76	2.76	210	16	3,360
§ 312.315(c) and 312.305(b); Number of submissions related to expanded access and treatment of an intermediate-size patient population	9	1	9	120	1,080
§ 312.320(b); Number of submissions related to a treatment IND or treatment protocol	1	1	1	300	300
Total					3,254,606

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 5—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR BIOLOGICS (CBER) [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
§ 312.52(a); Sponsor records for the transfer of obligations to a contract research organization	75	1.40	105	2	210
§ 312.57; Sponsor recordkeeping showing the receipt, shipment, or other disposition of the investigational drug, and any financial interests	335	2.70	904	100	90,400

TABLE 5—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR BIOLOGICS (CBER) [1]—Continued

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
§ 312.62(a); Investigator recordkeeping of the disposition of drugs	453	1	453	40	18,120
§ 312.62(b); Investigator recordkeeping of case histories of individuals	453	1	453	40	18,120
§ 312.160(a)(3); Records pertaining to the shipment of drugs for investigational use in laboratory research animals or in vitro tests	111	1.40	155	* 0.5	78
§ 312.160(c); Shipper records of alternative disposition of unused drugs	111	1.40	155	* 0.5	78
Total					127,006

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
* 30 minutes.

Because we have received an increased number of IND submissions since the last OMB approval of the information collection, we have increased our estimate of the associated burden accordingly.

Dated: February 6, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–01962 Filed 2–11–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0163]

Hospira, Inc., et al.; Withdrawal of Approval of 12 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 12 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of March 14, 2019.

FOR FURTHER INFORMATION CONTACT: Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993–0002, 240–402–7945, *Trang.Tran@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 065343	Epirubicin Hydrochloride (HCl) Injection USP, 10 milligrams (mg)/5 milliliters (mL), 50 mg/25 mL, 150 mg/75 mL, and 200 mg/100 mL.	Hospira, Inc., 275 North Field Dr., Bldg. H1, Lake Forest, IL 60045.
ANDA 070562	Flurazepam HCl Capsules USP, 15 mg	Pharmaceutical Basics, Inc., 301 South Cherokee St., Denver, CO 80223.
ANDA 070563	Flurazepam HCl Capsules USP, 30 mg	Do.
ANDA 071808	Flurazepam HCl Capsules USP, 15 mg	Halsey Drug Co., Inc., 1827 Pacific St., Brooklyn, NY 11233.
ANDA 071809	Flurazepam HCl Capsules USP, 30 mg	Do.
ANDA 076827	Vinorelbine Injection USP, Equivalent to 10 mg base/mL.	Hospira, Inc.
ANDA 077736	Polyethylene Glycol 3350 Powder for Oral Solution, 17 grams/scoopful.	Breckenridge Pharmaceutical, Inc., 6111 Broken Sound Parkway NW, Suite 170, Boca Raton, FL 33487.
ANDA 085763	Glutethimide Tablets, 500 mg	Chelsea Laboratories, Inc., 896 Orlando Ave., West Hampstead, NY 11552.
ANDA 085791	Pentobarbital Sodium Capsules, 100 mg	Do.
ANDA 087297	Glutethimide Tablets, 500 mg	Phoenix Pharmaceuticals, Inc., 111 Leuning St., South Hackensack, NJ 07606.
ANDA 088819	Aristocort A (triamcinolone acetonide) Cream, 0.1%	Astellas Pharma U.S., Inc., Three Parkway North, Deerfield, IL 60015.
ANDA 089459	Glutethimide Tablets, 500 mg	Halsey Drug Co., Inc.