



# ***ALLEGiant HEALTH CUSTOMER INFORMATION GUIDE***

*Allegiant Health's mission is to earn the trust of every customer, every day, by developing, manufacturing and supplying premium quality, good value, over-the-counter (OTC) pharmaceutical products and nutritional supplements to the worldwide market through advanced technology, great teamwork, tireless dedication and execution of sound business practices.*



ALLEGiant HEALTH  
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Deer Park, NY 11729  
631-940-9000  
[www.allegiant-health.com](http://www.allegiant-health.com)



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Attachment: Product Grievance Report



## ALLEGIANT HEALTH CORPORATE HISTORY

*Allegiant is a proven sourcing partner for over 30 years.*

1995

Registered for pharmaceutical manufacturing business in the State of New York

1996

Opened for business in Hauppauge, New York after completing facility renovation and obtaining FDA and NYS regulatory clearance

1996

Formal entry into the U.S. marketplace with the shipment of acetaminophen products

2004

Allegiant Health receives USPTO Trademark for Health A2Z.

2010

Construction completed on the new 80,000-square-foot state-of-art manufacturing facility in Deer Park, NY while keeping the operation at the original facility in Hauppauge, NY.

2011

Production started at the new Deer Park Facility

2012

Opened a new 80,000 square foot distribution warehouse in Hauppauge, NY

2014

Allegiant Health was founded as an independent business entity from the original division of A&Z Pharmaceutical located in Deer Park, NY. FDA registered with CDER for manufacture, packaging and testing of OTC products.

2017

Allegiant Health registered with FSAN to manufacture and package Supplements

2017

Allegiant Health expanded into the Amazon marketplace.

2018

Allegiant Health receives USPTO Trademark for PerkUp energy booster.

2021

Allegiant Health closes operations in its Hauppauge, NY warehouse and opens operations in its new 70,000 square foot logistics warehouse in Deer Park, NY, located 3 doors down from corporate headquarters.

2023

Allegiant Health expanded into Walmart.com.



## General Information

Allegiant Health is a vision-driven organization that is widely recognized for expertise in the manufacturing and marketing of quality pharmaceutical and nutritional supplement products for better health. Our investments in leading-edge technologies and innovations have enabled Allegiant Health to quickly evolve into an industry powerhouse that offers 100+ OTC (over-the-counter) formulas and nutritional supplement products.

Allegiant Health's business platform will continue to emphasize a commitment to total customer satisfaction as a prominent player in the private label, contract manufacturing and brand development business verticals. We pride ourselves in extensive R&D, comprehensive marketing, meaningful consumer education and specialized promotional programs.

## Corporate Headquarters and Operational Facility

Allegiant Health  
75 North Industry Court  
Deer Park, NY 11729

Tel. (631) 940-9000  
Fax: (631) 940-9591  
website: [www.allegiant-health.com](http://www.allegiant-health.com)

## Key Contacts

Brian Li, President  
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## Establishment Registration

FDA CDER Registration #: 3001195380  
FDA FSAN Registration #: 10931458166  
UL Certificate Registration #: 12-79557  
New York State Board of Pharmacy Registration #: 033228

**Brief description of the facility**

Allegiant Health Corporate Headquarters and manufacturing facility is located in Deer Park, NY, which is located in the central part of Long Island. It is approximately 40 miles east from New York City. The plant is situated in an industrial business park, surrounded by both manufacturing and non-manufacturing businesses.

Total site area	86,000ft <sup>2</sup>
Administration	10,000ft <sup>2</sup>
Quality Control	1000ft <sup>2</sup>
Production	36,000ft <sup>2</sup>
Storage facility	27,000ft <sup>2</sup>
Infrastructure	1,000ft <sup>2</sup>

Allegiant Health logistics warehouse is also located in Deer Park, NY, 3 buildings west of our of Corporate Headquarters.

Total site area	70,000ft <sup>2</sup>
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**Allegiant Health Capacity**

- 8 billion Dose Manufacturing Capacity
- 60 million Unit Packaging Capacity
- 200+ OTC and Nutritional Supplement Products

**Allegiant Health’s Capabilities Include:**

- Prime private label manufacturer of National Brand Equivalent (NBE) OTC pharmaceuticals
- Contract pharmaceutical manufacturing and packaging
- FDA registered and fully compliant with cGMPs
- UL tested and certified
- Industry-leading R&D and technical support
- Global sourcing and cost reduction strategies
- Competitive pricing
- International logistics expertise

## Private Label

Private label over-the-counter (OTC) pharmaceuticals and nutritional supplements represent the fastest growing sectors of the healthcare market. By partnering with Allegiant Health, private label partners receive cost-effective, convenient solutions, as well as the confidence that their product is made precisely to the highest standards of quality.

Allegiant Health's portfolio includes over 100 over-the-counter (OTC) pharmaceuticals and supplements. Our scientists regularly create custom formulas that effectively meet specific market demands and adhere to the strictest quality guidelines and safety protocols of the FDA and GMP.

The Allegiant Health private label solution is complete:

- Customized pharmaceutical and supplement packaging
- Flexible container options
- Precision labeling
- Multiple reliable fulfillment options

Allegiant Health's product portfolio includes:

- Analgesics
- Cough & Cold
- Allergy
- Stomach & Laxatives
- Antacids
- Sleep Aids & Alertness Aids

## Contract Manufacturing

Contract manufacturers rely on Allegiant Health for efficiency, experience, and dependability. Our flexibility enables us to meet any partner's over-the-counter (OTC) pharmaceutical or nutritional supplement manufacturing expectations.

Allegiant Health applies first-class research and scientific expertise to the process of developing custom, innovative custom formulas. As with all production and manufacturing at Allegiant Health, stringent quality control, including testing and batch validation, ensures that all products meet the highest standards through every phase of development, execution and delivery.

Allegiant Health's contract manufacturing capabilities:

- Research and development
- Innovative and custom formulation
- Analytic testing methodologies
- Pilot batch validation
- Process optimization, validation and troubleshooting
- Flavoring technology
- Ready-to-ship inventory
- On-time delivery and logistics systems
- Contract marketing, packaging and fulfillment solutions

## Contract Packaging

Allegiant Health's state-of-the-art pharmaceutical and supplement packaging, design and distribution services are characterized by rigid protocols. These systems are in place to ensure that all products, packaging and labeling comply with product safety measures to complete satisfaction of customer requirements and Federal guidelines. Allegiant Health's manufacturing protocols are designed to promote rapid delivery with capabilities that can accommodate even the most aggressive production deadlines.

Allegiant Health is a full-service and dependable manufacturing partner with contract packaging capabilities including:

- Blister packaging
- Tamper-evident screw, snap and child-resistant safety closures
- Cardboard
- Experienced design and marketing team

Plus, rigid protocols such as:

- Product line isolation
- Third-party label compliance testing
- Batch testing

## Graphic Design

As part of a complete solution for our clients, Allegiant Health houses a full-service graphic design department with extensive experience building and supporting branding efforts. Being a market leader in over-the-counter (OTC) pharmaceutical and vitamin supplements, Allegiant Health recognizes that winning market share is accomplished through effective branding and superior, high-quality products. A product's presentation is often a key differentiator in the consumer buying process. Our highly skilled marketing department creates impactful branding approaches that communicate the quality of national brand equivalents and convey a sense of reliability and trust.

Allegiant Health's creative department is trained and experienced to understand customer goals. Our department is adept at creating brand marketing that perfectly matches the look and feel of nationally recognized brands, visually expressing quality, effectiveness and innovation. Our creative services team works closely with clients to distill and communicate their brand identities in the most compelling, market-smart manner. Design services are offered on a for-fee basis reflecting the level of work requested.

Design capabilities include:

- Logo design and identity creation
- Packaging and package design
- Point-of-Purchase (POP) display and structural design
- Marketing support collateral
- Trade show graphics
- Advertising and outreach
- Websites
- Video

All marketing communications follow the protocols and guidelines required by the FDA and other regulatory bodies.

## Distribution

Allegiant Health's inventory and distribution management center is an indispensable customer resource. The distribution center works in tandem with the production facility to ensure that customer goals are achieved from manufacturing through distribution.

This includes:

- Advanced computer technology
- Freight forwarding
- Inventory management
- Logistics management
- Ready-to-ship inventory
- Superior customer response
- Sustainable capacities
- Warehousing

## Freight Forwarding

Product distribution is never a second thought or a last-minute decision at Allegiant Health. Allegiant Health's freight forwarding professionals focus on accurate communication and on-time delivery, mitigating drayage costs and ensuring that products are available to the market virtually on demand.

Our highly trained distribution management and logistics experts negotiate with carriers to offer customers the most comprehensive, efficient and cost-effective methods of delivery.

## Customer Service

Allegiant Health listens to our clients. This enables us to achieve their goals, swiftly and accurately. Our Customer Service Representatives are available to assist with product information, product availability, product shipping information or whatever other assistance clients require. Maintaining a client's trust and satisfaction is our goal; it drives Allegiant Health's customer service philosophy.

We support our Customer Service Team through training and technology. We recently installed new computer systems that include advanced customer service software to quickly and accurately access all pertinent client information for immediate support. We ensure that we handle inquiries promptly, offering our clients exceptional turnkey solutions.

## Quality Assurance & Testing

Quality assurance and testing is a top priority at Allegiant Health. Every year we invest significant resources into extensive training programs making certain our associates achieve the highest levels of quality execution in operations and ensuring that premium, high-quality products will be consistently manufactured.

Allegiant Health's operational activities are constantly monitored by the company's Quality Assurance Team, ensuring complete conformance with cGMP standards, as required by the FDA. The consistency, efficacy and safety of Allegiant Health's manufacturing processes are accomplished by implementing industry-leading,

comprehensive quality assurance protocols. The company's QC Laboratory is equipped with a variety of highly sophisticated instrumentation and technology including High Pressure Liquid Chromatography (HPLC), Infrared Spectrophotometry (IR), Ultra Violet-Visible Spectrophotometry (UV-Vis), Dissolution Apparatus and Accelerated Stability Chamber. All product testing is performed according to official compendia and the highest industry standards.

Allegiant Health's Quality Assurance and Testing Protocols feature:

- cGMP compliance and investigational testing
- Quality assurance validation and documentation
- Raw materials and finished product testing
- Validation and stability testing

### Quality Control

The Quality Control Laboratory is a key component and the centerpiece of Allegiant Health's commitment to quality. This state-of-the-art facility is fully equipped with advanced instrumentation including: HPLC, UPLC, GC, Dissolution, FTIR, Atomic Absorption Spectrometer and Fluorescence Spectrometer. The lab has an exceptional staff of chemists and scientists with educational pedigrees ranging from BS degrees to PhDs.

The primary lab functions are focused on quality control of raw materials and finished goods including:

- Analytical method development and validation
- Verification of compendial and non-compendial analytical procedures
- Stability programs under accelerated and room temperature
- Analytical support for drug development
- Process and cleaning validation

### Regulatory Affairs

Allegiant Health is fully compliant with all applicable State and Federal regulations. The company is a registered and audited cGMP facility. Other regulatory specific data points:

- FDA: Code of Federal Regulations Title 21, Part 211; current Good Manufacturing Processes for Finished Pharmaceuticals
- Certified through UL's (formerly STR/Shuster) "Retail Certification Program" and holds the A-CLASS and STR-R cGMP OTC Drugs Registered Marks
- FDA CDER Facility Number: 3001195380
- FDA FSAN Facility Number: 10931458166
- New York State Board of Pharmacy Facility Number: 030595

### Compliance with Federal, State, and Local Regulations

Allegiant Health assures compliance with all US Federal, New York State, and Suffolk County regulations in the production and distribution of our OTC and Nutraceutical products to our direct customers.

Customers are responsible for assuring compliance with all US Federal, State, and Local regulations for the areas in which they distribute/sell Allegiant Health products, including complying with the California Safe Drinking Water and Toxic Enforcement Act of 1986.

## Allegiant Health Shipping Guide

Allegiant Health is dedicated to providing accurate and controlled shipping operations between our organizations.

To facilitate a smooth process and to clarify the roles and responsibilities of each organization, we would like to present the following general shipping terms and conditions. We encourage you to read the following in its entirety.

**Preferred Carriers** – Logistics is a pivotal aspect of our day to day business and we work to ship your requested product to you as efficiently as possible. Your feedback on how to do this is very important. If you find that there are certain carriers that consistently meet your company’s expectations with regard to honoring set appointments, causing very little damage to freight, or simply offering a level of service that sets them above the rest, please advise us and we will make every effort to work with them. Conversely, if there are carriers that you wish us to avoid, and you choose not to do business with them, we will make sure not to route any shipments through those identified organizations.

**Free on Board (Collect Customers)** – Our goal is to advise our “F.O.B.” customers the same day that your order has been pulled and is ready for pick up. We do this via e-mail, unless otherwise specified. We ask that the Bill of Lading for the Carrier assigned to pick up your shipment be forwarded by e-mail to: [custrelations@allegiant-health.com](mailto:custrelations@allegiant-health.com) so it may be provided to our shipping department. We do hold our F.O.B. customers to the expectation that product be picked up from our facility within 5 business days of our initial contact. We will attempt to follow up with you if there has been no response. However, after the 5th business day has elapsed, the product will be returned to stock at a \$25 per pallet restocking fee or if requested, held complete for a \$25 per day storage fee.

- As an additional service to our Free on Board customers, we can provide “One Time” shipping quotes using our network of Broker/Carriers to provide a wide range of delivery and pricing options so that you may avoid negotiating with freight companies. We work with many national carriers, as well as some of the most trusted Brokerage firms in the freight industry. We will you provide a list of options which includes the carrier, the cost, and the transit time for each. Once you make a selection, our Logistics department will arrange for the pickup and delivery. The quoted cost would then be included on your invoice in addition to a small fee of \$25.00 for Handling. *(Please see the example below\*)*

<u>CARRIER</u>	<u>COST</u>	<u>TRANSIT TIME</u>	<u>HANDLING</u>	<u>TOTAL INVOICED</u>
Central Transport	\$130.78	3 days	\$25.00	\$155.75
Roadrunner Freight	\$128.49	4 days	\$25.00	\$153.49
YRC Freight	\$168.88	2 days	\$25.00	\$193.88

**Freight Charge Backs** – For our customers that currently hold a “Prepaid” status for your contracted freight arrangements, we have made a concerted effort to ship to you as efficiently and economically as possible by selecting the most reliable carriers and absorbing any of the pricing fluctuations that are notorious in the shipping industry. That said, on occasion it is necessary to invoice customers directly for any additional charges incurred at the time of delivery that are above and beyond the agreed upon terms of our contract. These additional charges will include the following unforeseen freight costs, as well as any other fees above the routine terms:

- Lumper Fees** – There is an additional cost for the carrier to stand down as outside laborers are used to unload a trailer. This cost will constitute a charge back as invoiced by the carrier.

- **Sort and Segregate** – When multiple items are shipped on a single pallet, many receivers will require the driver to handle the product and place each item on a separate pallet. The amount of handling required correlates to the number of items shipped on the pallet. If not advised that this is a required service at the time of contract this will constitute a charge back as invoiced by the carrier.
- **Detention Fees** - All of our carriers are required to contact a customer’s receiving department and arrange for a “Delivery Appointment”. The average carrier will allot anywhere from and 60 to 90 minutes beyond the set appointment before they begin charging for being held in queue to unload their freight. The cost of this hold time will constitute a charge back as invoiced by the carrier.
- **Shipments Redirected in Transit** – On occasion we may have a customer with multiple warehouse locations that may be unable to accept freight at their designated delivery site at the appointed time. There may be a request to redirect the shipment to secondary site that can handle the volume. The additional cost incurred for this change will constitute a charge back as invoiced by the carrier.
- **Other**- Any other non-routine charges incurred will constitute a charge back as invoiced by the carrier.

**Reporting Shipping Discrepancies** – In an effort to streamline the reporting process for Damages, the receipt of incorrect product, or short shipments, Allegiant will provide a copy of our Product Grievance Report. We ask that we be advised of any discrepancy within 72 hours of receipt of your product by submitting the appropriate documentation to [orders@allegiant-health.com](mailto:orders@allegiant-health.com). Your submission will be acknowledged within 24 hours and the progress of your claim can be tracked by referring to your Purchase Order number. Allegiant will provide a follow up report within 3 business days of grievance receipt. It is important to note that we will not acknowledge any claim unless submitted in writing by using the supplied Product Grievance Form or other similar reporting form. Any payments submitted short will result in invoicing being submitted to your Accounts Payable department for the pending balance.

#### **Shipment Verification Policy – Proof of Delivery**

As a valued customer of Allegiant Health, we want to assure accurate deliveries of our products to you. To assure accuracy of each shipment, Allegiant prepares internal documents for each shipment, including a Pick Slip which is hand checked and verified, a pallet sheet summary, and a Bill of Lading listing number of cases, weight and number of pallets. When the carrier accepts the shipment from our dock, it is signed and accepted by the carrier as complete and intact.

This combination of documents and verifications should ensure accurate delivery. However, Allegiant recognizes that mistakes at Allegiant, or damages or loss during transport, can occur. Therefore, to properly investigate errors or transport issues, we must rely on our customer’s verification **at time of receipt**. This verification of case count and case damage must be documented on the carrier’s Proof of Delivery (POD) form at the time of delivery, as this is the only means by which we can assure proof of delivery and condition of shipment with our carrier. Please note that your signature on the POD exonerates the carrier of any liability and therefore leaves Allegiant with no recourse with the carrier.

As such, once a shipment is received into your warehouse, and the POD is signed as complete and without damage, no further damage or shortage/overage report can be processed by Allegiant. Of course, if upon opening cases later, you should identify a unit issue, we will process and investigate that issue immediately upon your identification and report to us.

We require that all POD signatures and notations represent final receipt condition, and as such we must require you to note any shipment issues on the POD. As well, to expedite a grievance response, we strongly encourage you to use our Product Grievance Report Form.

## Forecast / PO Scheduling Optimization

As part of our efforts to assure that you receive your products on time and as needed, Allegiant Health is requesting a rolling forecast and secure PO schedule from you. This forecast, and associated POs, will allow Allegiant to allocate the proper resources to satisfy your needs, thereby assuring an optimal production and delivery schedule.

### ***For our Private Label, Bulk Order, and Contract Packaging customers,***

In order to assure the highest level of on-time delivery, we ask that you partner with us in planning and forecasting your needs.

For our customers who already provide forecasts, we thank you.

For our customers who do not currently provide forecasting, Allegiant is requesting submission of a minimum, 6 month rolling forecast with POs due a minimum of 30 days prior to your requested ship date. We request submission of this forecast as soon as possible, but no later than January 15 to secure your Q1 orders.

If you need help forecasting, our Planning Department can build a forecast for you based upon your order history. If you wish to enlist our help, please contact our Customer Service Department at [orders@allegiant-health.com](mailto:orders@allegiant-health.com) and request a forecast. Once you receive the forecast, we ask you to make any necessary adjustments and submit with approval within 15 business days.

Unfortunately, customers who do not provide a forecast will have their order status placed in the “made-to-order” category which may result in delays of availability, as we will await your order before placing material requisitions and/or production time slots.

We will continue to solicit a forecast from you on a routine basis which, if you accept, will move your product out of the “made-to-order” category and back into the scheduled queue. Please understand that “made-to-order” production and delivery will have extended lead times.

### ***For our Health A2Z customers,***

Allegiant makes every effort to assure inventory of all Health A2Z products, however, during times of heavy ordering or delays from material suppliers, a forecast will help assure that your inventory is allocated and available.

### ***Finally, for all of our customers,***

Allegiant understands that emergency situations can arise, and your inventory can run unexpectedly low. During these times, we encourage you to submit emergency POs for our “made-to-order” queue or available stock inventory. In response, we will expedite your order as quickly as is feasible and will provide you with a target date for delivery.



### **Label Creation/Change Policy**

As a service to our customers, Allegiant Health offers support for product label creation and changes for Private Label customers. This offer is made to our customers for products manufactured and/or packaged by Allegiant and distributed to your company.

Allegiant employs experts in both label content requirements and label artwork. Our internal staff has over 20 years' experience creating compliant and artistically mastered labels. Our team will work with your team to prepare and approve your new labels.

If you are interested in taking advantage of this service, please contact our Quality Department at 631-940-9000 x139. If you choose this option, we will provide a quote for the service, as this is a fee for service process.

If a needed label change results from an error in label drug fact content by Allegiant or a change to an Allegiant supplier or material, there is no fee for this service.

If the label change is initiated by you (ie: new logo, new name, colors, layout), or if the change is required by an FDA regulatory change, processing the change is subject to additional fees including labor and hard costs.

### **FDA Label Submission Policy**

As per FDA requirements, all OTC labels must be submitted prior to market introduction. Subsequently, if any changes are made, the revised labels must be submitted annually to the FDA. If there are no changes, an annual "no change" certification must be made with the FDA.

As a service to our customers, Allegiant Health offers annual label submission for Private Label customers through the FDA SPL portal. This offer is made to our customers for products manufactured and/or packaged by Allegiant and distributed to your company.

Any label changes performed in a calendar year, for a submitted label, must be re-submitted by the end of June (for changes made between January and June) and by the end of December (for changes made between July and December). As well, any new labels for new products must be submitted immediately. If there are no changes to your labels in the calendar year, resubmission is not required.

Allegiant will submit the labels and verify receipt and approval.

Once Allegiant submits your labels, you will receive a communication from us indicating that submissions have been completed.

If the label change resulted from an error in label creation by Allegiant or a change to an Allegiant supplier, there is no fee for this service.

If the label change was initiated by you, or if the change is required by an FDA regulatory change, the submission is subject to additional fees.

To take advantage of this service, please contact our Quality/Regulatory staff at 631-940-9000 x139.

## **Regulatory Support Policy**

As a service to our customers, Allegiant Health offers Regulatory Support to help you navigate through the hurdles of the submission and approval process.

Allegiant employs a highly skilled Regulatory staff with over 30 years of experience in Domestic and International registrations and submissions. Your registration process requires significant documentation and a professional submission package. We offer support completing International Dossiers, acquisition of FDA Certificates of Pharmaceutical Products, and a complete support data package including product specifications, stability data, and other required documents.

To take advantage of this service, please contact our Regulatory Affairs staff at 631-940-9000 x139.

Associated fees, timelines, and availability are determined by the scope of your needs. A custom proposal will be generated for your review and approval. We look forward to offering you an aggressive advantage in this process.

Our services are available to all our customers. As you seek to grow your business, we are here to help. Your success is our success.

## **Stability Support Policy**

As a service to our bulk customers and special packaging customers, Allegiant Health offers stability support for your final packaged products. Be assured that when you purchase our bulk products, ongoing stability is conducted in bulk configuration to support our bulk expiry dating. However, once you package your final product in specialized packaging, Allegiant is still here to assist you in completing your FDA required ongoing stability needs.

Allegiant's QC Laboratory is staffed with highly trained QC analysts ready to generate and execute a Stability Protocol for you. Our team will prepare your customized study for your products in your packages. Reports are generated at each stability test station and our QA staff oversees all activities for the ongoing study.

To take advantage of this service, please contact our Quality Department at 631-940-9000 x139.

Associated fees, timelines, and availability are determined by the scope of your needs. A custom proposal will be generated for your review and approval. We look forward to offering you an aggressive advantage in this process.

This service is available to all our bulk customers and to any customers seeking specialized packaging.

## **e-Commerce Support Policy**

Given the complex landscape and continually evolving requirements, Allegiant Health may not have the information requested by various e-commerce platforms. Our document package satisfies all FDA requirements; however, many online platforms require documents outside of FDA requirements.

We encourage any customers seeking to list their products online to thoroughly investigate the requirements, and to recognize that they may need to make further investments to satisfy those requirements. Any activities and investments to satisfy online listing requirements are the sole responsibility of our customer.

## Our Vision

*Allegiant Health's vision is to become the premier trusted source for best-in-class OTC (over-the-counter) pharmaceuticals and nutritional supplements, as well as an organization that is globally recognized for innovation and customer satisfaction.*

*Allegiant Health will continue to leverage our worldwide manufacturing and marketing resources to provide customers with unmatched core competencies that result in premium quality, high-value products and world-class customer service. Our commitment to excellence, quality and innovation will ensure that we will continue to improve our daily performance, even as we focus on consistent, long-term, financial growth.*

*It is our intention that this guide will improve communication and provide you with the necessary foundation for making sound sourcing decisions. As always, we remain available for all questions and comments*