

April 15, 2009

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: COMMENTS OF GS1 AND GS1 US
Docket No. FDA-2009-D-0001
*(Draft) Guidance for Industry (on) Standards for Securing the Drug Supply Chain-
Standardized Numerical Identification for Prescription Drug Packages*

To Whom It May Concern:

We write on behalf of GS1 and GS1 US. We are pleased to have this opportunity to respond to the Request for Information made in Docket No. FDA-2009-D-0001, titled "Guidance for Industry (on) Standards for Securing the Drug Supply Chain—Standardized Numerical Identification for Prescription Drug Packages." We are encouraged by and support expeditious action by the FDA in this vital standards-setting endeavor.

We congratulate and commend the FDA for its on-going commitment to the examination of healthcare applications of supply chain technology, as well as your commitment to support industry in the development of standards.

If we can be of any further assistance, please do not hesitate to contact us.

Sincerely,



Christopher Adcock
President Healthcare GS1 Global Office



Dennis W. Harrison
President, GS1 Healthcare US

Enclosure: April 15, 2009 comments on Docket No. FDA-2009-D-0001



GS1 COMMENT

**UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
[Docket No. FDA-2009-D-0001]**

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EXECUTIVE SUMMARY

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The FDA has continually demonstrated their on-going commitment to the examination of healthcare applications of supply chain technology, as well as their commitment to support industry in the development of standards. As the FDA moves forward, GS1 recommends that the FDA not over specify technology and tools. Instead, we encourage the FDA to adopt a comprehensive standards system that encompasses the necessary suite of *foundational standards* (e.g., identifiers; data attributes; etc.), and then support industry in developing any additional *application standards* that may be necessary for healthcare supply chain needs. Specifically, we recommend that the FDA adopt the GS1 System, and lend its considerable support to industry through engagement with GS1 Healthcare and GS1 Healthcare US. This will enable the FDA to leverage existing standards and standard development processes to support an efficient and effective transition, and to encourage wider adoption in the user community.

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Standardized Numerical Identifiers

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Characteristics & Considerations: Standards-based identification has been widely implemented in many industry sectors for several decades. For the best results, the standardized identifier for prescription drugs should incorporate the conventional wisdom gleaned from those experiences. GS1 highlights the following considerations for the standardized identification system for prescription drugs:

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- **GLOBAL:** Global standards are essential in today's complex markets where supply chain lines are blurring and channels of distribution for various sectors are overlapping.

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- **SERIALIZED:** Where greater visibility than GTIN or Lot Level are required and the unique item or instance is needed, this can be enabled with serialization. Serialized identification numbers (i.e., standards-based numbers that identify a specific instance of a pharmaceutical product) could be used to enhance supply chains tools like track and trace.

- 34 ➤ **RULES & SUPPORT:** Users need standards and rules for generating identification
35 numbers, as well as support for assigning individual numbers pursuant to the
36 standards in order to maintain the uniqueness of prescription drug identification
37 numbers.
- 38 ➤ **EMBEDDED INFORMATION:** It is best to include as minimal pharmaceutical
39 product information in the identifiers itself as possible. Product information is best
40 managed via standardized attributes stored in databases.
- 41 ➤ **MACHINE READABLE & HUMAN READABLE:** Markings should be both
42 human readable and encoded for automatic data capture wherever possible. Where
43 human readable markings are not possible, standards should be developed for how
44 to convey the information.

45 **Existing Standards:** The GS1 System’s comprehensive suite of standards provides an
46 excellent framework for identification in the prescription drug supply chain. Within the GS1
47 System of standards, the GTIN (Global Trade Item Number) is used to identify individual
48 units of prescription drugs. In fact, the GTIN has already been chosen to uniquely identify
49 pharmaceutical products in 65 countries worldwide. Beyond the GTIN, other GS1
50 Identifiers are currently being used by the pharmaceutical sector as well, including most
51 notably the SSCC (Serial Shipping Container Code) to identify logistic units.

52 **Implementation:** The *Labeler Code* is an identifier assigned by the FDA and embedded into
53 the National Drug Code (NDC) and the National Health Related Item Codes (NHRIC) to
54 identify the company. The current practice for prescription drug identification in the United
55 States is to embed the NDC in the GTIN string. In order to do that, GS1 US has reserved a
56 placeholder in our *Company Prefix* numbering system so that GS1 *Company Prefixes* for
57 pharmaceutical companies is consistent with their NDC *Labeler Code*.

58 **Harmonization with Other Countries:** Many countries have implemented national
59 identification systems for prescription drugs (e.g., in the United States, prescription drugs are
60 assigned NDCs). These systems have differing degrees of interoperability with GS1’s global
61 product identifier called GTIN. In order for data, systems and networks of the future to
62 interoperate, product identification syntax and allocation rules must increasingly be
63 harmonized; allowing trading partners to use subsequent standards (such as GS1 EPCIS and
64 Discovery Service) to realize additional patient safety measures and supply chain efficiencies.
65 Companies using the GTIN to identify prescription drugs integrate those national identifiers
66 into their product identification schemes. To date, sixty five countries support the use of
67 GTIN, most notably, the United Kingdom, the Netherlands, Australia, Russia and Turkey.
68 Efforts to achieve even broader global adoption are on-going.

69 **Prioritization**

70 The prescription drug supply chain needs a comprehensive set of standards for *prescription*
71 *drug identification*. Specifically, the prescription drug supply chain needs standardized
72 identification numbers (GTIN), standardized attributes such as AI (21) for Serial Number,
73 and standardized data carriers such as GS1 DataBar and GS1 DataMatrix (a two-dimensional
74 bar code). These three sets of standards are foundational standards that enable the supply

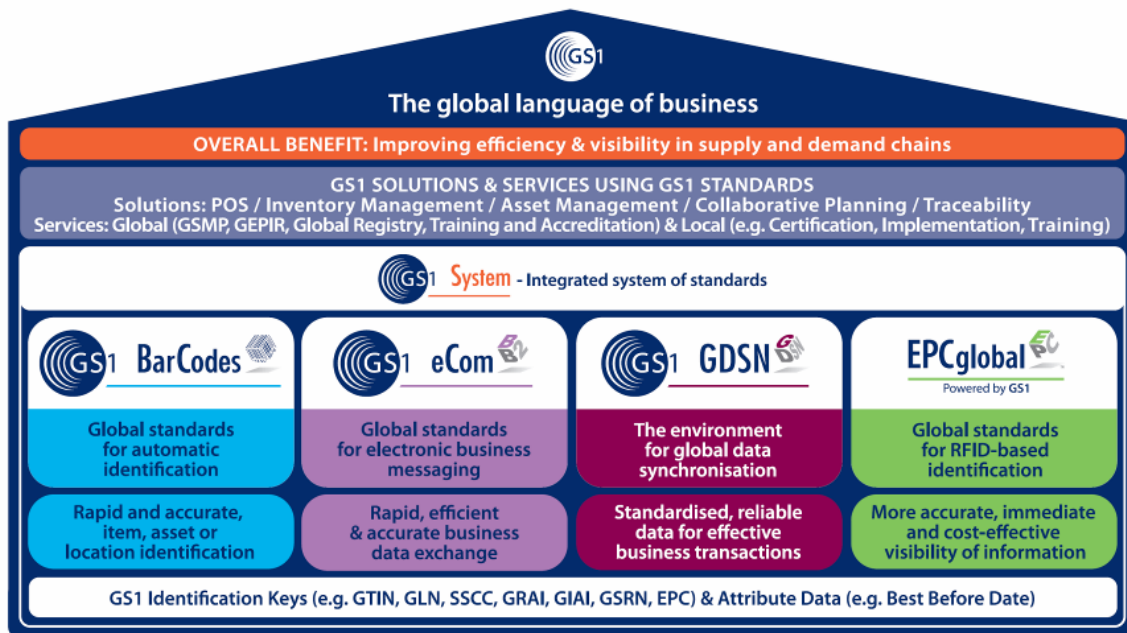
75 chain to use bar code or additionally RFID technology for prescription drug identification.
76 These foundational standards must be implemented first because they provide the backbone
77 for *track and trace of prescription drugs*. Once those standards are implemented, industry can
78 then turn to the development of application standards like master data exchange then track
79 and trace.

80

81 **BACKGROUND**

82 **WHO IS GS1?**

83 GS1 is a leading global organization dedicated to the design and implementation of global
84 standards and solutions to improve efficiency and visibility in supply and demand chains.
85 GS1 and its subsidiaries and partnerships connect companies with standards-based solutions
86 that are open, consensus-based and universally endorsed. From bar codes, RFID,
87 eCommerce, data synchronization, to business process automation standards, GS1 is the
88 trusted source to deliver innovative standards, services and solutions for business' most
89 pressing supply chain challenges.



90

91 GS1 is a fully integrated global organization, with 108 Member Organizations serving over a
92 million companies doing business across 150 countries. GS1 US [formerly the Uniform Code
93 Council (UCC)] is the Member Organization of GS1 that serves members in the United
94 States. As such, it is the national implementation organization of the GS1 System in the
95 United States. GS1 US currently serves over 200,000 U.S. member companies -- 16,000 of
96 which are in healthcare.

97 **NOTE:** EPCglobal Inc™ is a joint venture between GS1 and GS1 US. EPCglobal is an
98 open, subscription-based, not-for-profit standards organization that develops and oversees
99 the standards for the EPCglobal Network™. Neutral and consensus-based, EPCglobal is
100 industry's trusted partner for driving the global adoption and implementation of the
101 EPCglobal Network across industry sectors. (EPCglobal US is the member organization of
102 EPCglobal Inc that serves Subscribers in the United States.)

103

GS1 & HEALTHCARE

104 GS1 is the leading global standards organization in the healthcare industry. In 65 countries
105 worldwide, GS1 standards have been chosen to uniquely identify pharmaceutical products.
106 In addition, national and regional healthcare associations and organizations around the world
107 have endorsed GS1 standards, including regulatory bodies in the United States, Japan and
108 the United Kingdom. GS1 standards will improve patient safety and reduce costs in the
109 global healthcare supply chain. Automatic pharmaceutical product identification on all
110 packaging levels and full traceability promotes a safe and secure supply chain by providing
111 greater visibility, accuracy and efficiency for the benefit of all parties involved. Preventing
112 medical errors and combating counterfeiting are top-of-mind concerns facing the healthcare
113 sector, and GS1 standards are helping to solve these issues.

114 GS1 supports the Healthcare community through its GS1 Healthcare global initiative as well
115 as local support initiatives like GS1 Healthcare US, in the United States. GS1 Healthcare is a
116 voluntary, global user community bringing together all healthcare stakeholders, including:
117 pharmaceutical and medical device manufacturers, wholesalers and distributors, group
118 purchasing organizations, hospitals, pharmacies, logistics providers, governmental and
119 regulatory bodies, and associations. The mission of GS1 Healthcare is to lead the healthcare
120 sector to the successful development and implementation of global standards by bringing
121 together experts in healthcare to enhance patient safety and supply chain efficiencies. The
122 vision is to become the recognized, open and neutral source for regulatory agencies, industry
123 organizations and other similar stakeholders seeking input and direction for global standards
124 in healthcare for patient safety, supply chain security & efficiency, traceability and accurate
125 data synchronization.

126 GS1 Healthcare was created to drive the development of GS1 standards and solutions to
127 meet the needs of the global healthcare industry, and to lead the healthcare industry to the
128 effective utilization and development of global standards with the primary focus on
129 automatic identification to improve patient safety. The objectives of GS1 Healthcare are to:

- 130 ➤ Work with key partners in the global healthcare supply chain to develop and
131 optimize the use of global standards to enhance accurate and fast movement of
132 goods from manufacturer to distributor to healthcare providers (such as hospitals or
133 public pharmacies).
- 134 ➤ Facilitate awareness in the healthcare sector of new technologies and methods of
135 doing e-business.
- 136 ➤ Provide advice and recommendations to GS1 on issues and opportunities in the
137 healthcare sector.
- 138 ➤ Promote best practice implementation of the GS1 System in the healthcare industry.
- 139 ➤ Promote the implementation of GS1 voluntary, global business standards
140 throughout the healthcare sector.

141 **COMMENTS REGARDING FDA DRAFT GUIDANCE FOR**
142 **STANDARDIZED NUMERICAL IDENTIFICATION FOR**
143 **PRESCRIPTION DRUG PACKAGES**

144 **NDC AND GTIN Co-EXISTENCE**

145 GS1 appreciates the FDA's willingness to continue to support the long running practice of
146 embedding the NDC in the Global Trade Item Number or GTIN (GS1's global Product
147 Identifier) number pool. This allows manufacturers to express the local identifier (NDC) in
148 a format that:

- 149
- 150 • Will not overlap with any GTIN assignments anywhere in the world
 - 151 • Permits the industry to move in the direction of master data alignment per
152 harmonized GTIN allocation rules
 - 153 • Provides a standard syntax similar to GTIN for structuring an EPC query
 - 154 • Allows GTIN to be used in the global market place without creating artificial barriers
 - 155 • Preserves the longer term usability and uniqueness of the GTIN and associated
156 interoperable standards

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158 GS1 will work with the industry and FDA to understand the potential differences in
159 allocation rules and the potential ramifications to longer term strategies for globally unique
160 GTINs.

161 **CONSOLIDATING DUPLICATE AUTOMATIC IDENTIFICATION**
162 **INFORMATION ON PRESCRIPTION DRUGS**

163 The industry's predominate response to the FDA's guidance on serialized identifiers is to use
164 the GS1 DataMatrix or additionally EPC/RFID carriers. Both of these carriers incorporate,
165 redundantly, the pharmaceutical product identification that exists in the mandatory linear bar
166 code (i.e., the linear bar code required per 69 FR 9120, "Bar Code Label Requirement for
167 Human Drug Products and Biological Products")

168

169 As all parties in the U.S. supply chain may be required, at some point, to read these other
170 carriers, we feel that coding the Product Identifier (NDC) twice may be redundant. As label
171 space is at a premium, especially, for very small packages (pre-filled syringes, ampoules, etc.);
172 it would be a benefit to the industry, providers and patients, for manufacturers to be able to
173 make better use of the label space taken up by redundantly coded pharmaceutical product
174 identifiers.

175

176 GS1 recommends that the FDA harmonize this new guideline for NDC-based SNI with
177 existing regulations that require manufacturers to apply the NDC via linear barcodes.

178

EXEMPTION / WAIVER PROCESS

179 We strongly urge the Agency to include a formal Waiver or Exemption process,
180 such as the one included in 69 FR 9120, "Bar Code Label Requirement for Human
181 Drug Products and Biological Products".

- 182 1. Existing marking exemptions in the referenced legislation should be
183 preserved and brought-forward into this guidance document.
- 184 2. At minimum, the following categories of drug products should be
185 exempted, at least in the initial phases until further studies can be
186 completed. There are complex issues surrounding each of these categories
187 and industry consensus is lacking for example:
 - 188 a. Non-prescription OTC drug products
 - 189 b. Kits that contain any drug product
 - 190 c. Combination Drug / Device Drug products that are custom-made
191 for a specific patient (such as anti-allergy extracts manufactured for
192 one patient)
- 193 3. Manufacturer / Brand Owner should be provided the opportunity to
194 request exemptions or waivers for specific products based on facts
195 submitted.

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FOSTERING FURTHER INDUSTRY INVESTMENTS IN SERIALIZATION

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DATA CARRIERS

198 GS1 recommends that the FDA's CPG is amended to cover both RFID and barcode (e.g.
199 data carrier agnostic). This would help support the efforts of having more companies
200 perform serialization pilots.

201

INCLUSION OF ADDITIONAL INFORMATION IN THE SNI

202 GS1 supports the FDA's decision to not include additional data (Expiration Date, Lot or
203 Batch Number) in the Standardized Numerical Identification (SNI). GS1 standards make a
204 distinction between Identifiers (Keys) and additional data (attributes), both referred to as
205 GS1 Application Identifiers in the GS1 General Specifications) that may be represented in a
206 data carrier (Linear Bar Code, GS1 DataMatrix, RFID, etc.). In cases where there is a need
207 to represent data in addition to the SNI; GS1 recommends the use of GS1 Application
208 Identifiers. The GS1 General Specifications details how GS1 Application Identifiers are
209 encoded into GS1 linear bar code, GS1 DataBar™ and GS1 DataMatrix carriers. The
210 EPCglobal Tag Data Standard details how GS1 Application Identifiers are encoded into
211 EPC/RFID tags.

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**AIDC APPLICATION STANDARDS FOR IDENTIFICATION AND
MARKING OF HEALTHCARE PRODUCTS**

214 GS1 Healthcare has facilitated a cross-functional, global team of 90+ members for the past
215 2 years to define a tiered approach to marking of Healthcare items, with the amount of data
216 carried in AIDC appropriate to the intended use of the product. This work is currently in
217 the final phase in the standards approval process (GSMP) and will ultimately be integrated
218 into a new revision of the GS1 General Specifications document.

219 **COMMENTS REGARDING QUESTIONS POSED IN THE DRAFT**
220 **GUIDANCE (DOCKET FDA-2009-D-0001)**

221 **FDA'S REQUEST FOR INFORMATION**

222 **FDA Question 1: Identifiers for pallet and intermediate**
223 **levels of packaging**

224 *We believe that the serialized National Drug Code (sNDC) described*
225 *in the draft guidance is appropriate for package level identification for*
226 *most prescription drugs; however, it might not be useful at the pallet*
227 *or other intermediate level, such as the case. We did not receive many*
228 *comments related to standards for numerical identification at the case*
229 *or pallet level and would like broader input on this subject. Please*
230 *comment on whether there are any standards that would be*
231 *appropriate for serialization or other numerical identification at the*
232 *case or pallet level.*

233 Packaging levels exist for many reasons; as a result, not all levels are intended to be identified
234 or marked. While cases and pallets are identified and marked (with bar codes or RFID) to
235 aid logistics processes, some intermediary packaging levels, such as sleeves or bundles, exist
236 to aid in packaging processes only and are not meant to be identified individually. The GS1
237 System of standards makes available two identifiers that can be used at intermediate levels of
238 packaging (Case and Pallet). The GS1 System of standards makes a distinction between a
239 trade (saleable) item and a logistics unit. A trade item is typically listed in the manufacturer's
240 product catalog, while a logistics unit exists to aid in shipping and handling goods in transit
241 and storage.

242
243 Typically, trading partners use GS1's Global Trade Item Number, or, GTIN to identify trade
244 items and the GS1 Serial Shipping Container Code, or, SSCC to identify logistics units. It is
245 up to the owner of the item (typically, the manufacturer) to determine whether an item is to
246 be considered a trade item or logistics unit (GS1 publishes guidelines to aid the industry).

247
248 A third GS1 Identifier could also be used by portions of the supply chain. In the case that
249 the packaging layer is intended to be returned to the shipper for re-use, the GS1 Global
250 Returnable Asset Identifier, or, GRAI may be used. An example of this is Wholesaler totes,
251 which are returned to the Wholesaler. The GRAI is used by the Wholesaler's customer (or
252 the Wholesaler during pickup) to identify the totes that belong to the particular Wholesaler.
253 Wholesalers may also use the GRAI internally to direct totes to the proper picking and
254 shipping points within their operations.

255 The GTIN, SSCC and GRAI are members of the family of GS1 Identifiers available for use
256 by the pharmaceutical industry. The GS1 System supports nine global Identification
257 Numbers. Each GS1 Identification Number supports a distinct type of supply chain item
258 (i.e., trade item, service, location, logistic unit, returnable container, etc.) and provides a link
259 between the item and information pertaining to it.

GS1 Identification Number	GS1 Identification Number Title	Type of Supply Chain Information
GTIN	Global Trade Item Number	<i>trade items</i>
GLN	Global Location Number	<i>locations & trading partners</i>
SSCC	Serial Shipping Container Code	<i>logistics units</i>
GIAI	Global Individual Asset Identifier	<i>individual assets</i>
GRAI	Global Returnable Asset Identifier	<i>returnable assets</i>
GSRN	Global Service Relation Number	<i>service relationships</i>
GDTI	Global Document Type Identifier	<i>document types</i>
GSIN	Global Shipment ID Number	<i>shipment</i>
GINC	Global ID Number for Consignments	<i>consignment</i>

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261 The GS1 System provides clear, structured data standards and allocation rules for generating
262 GS1 Identification Numbers.

263 We recommend that the FDA allow the use of the GTIN, SSCC and GRAI for layers of
264 packaging. We also recommend that the party under which an item is packaged be allowed
265 to make the decision (Manufacturer, Wholesaler, Re-packager, etc.) as to which identifier to
266 use based on industry application standards.

267 We recommend also that the requirements for all packaging levels must be addressed in a
268 single guidance document, or in separate guidance documents all written and released at the
269 same time—and consistent with one another.

- 270 a. For instance: the guidance should address the Agency expectations on assignment of
271 SNI's to Cases, Pallets, and other collections of products.
- 272 b. Different solutions for SNI by packaging level would not be acceptable to industry—
273 the packaging hierarchy can be completely modeled using existing GS1 standards
274 today, and FDA should simply adopt these existing, approved, consensus standards.

275 **FDA Question 2: SNI format; Numeric vs. Alpha-numeric**

276 *Some comments recommended that the SNI allow for alpha-numeric*
277 *serial numbers in order to increase the choices for the numbers.*
278 *FDA's draft guidance recommends that the SNI for most prescription*
279 *drug packages be an sNDC, consisting of the NDC plus a unique 8-*
280 *digit numerical serial number. Given the FDA recommendation for*

281 *SNI, please comment on the necessity of having the serial number*
282 *allow for alpha-numeric possibilities and under what standards this*
283 *might be achieved.*

284 A number of products in many industries are and will be identified with serial numbers.
285 Today, supply chains intermingle at various points. Manufacturers produce both
286 prescription and non-prescription products. Wholesalers manage goods from a number of
287 industries. Healthcare Providers and Retailers purchase and use products from many
288 industries (Pharmaceuticals, Medical Devices, Food, paper goods, services). At times, the
289 industry makes use of computer applications that are not necessarily industry specific and
290 need to process and report on all products purchased, inventoried or sold. We believe that a
291 specified field length and character limits may be too prescriptive and may restrict healthcare
292 companies as they manage the diverse portfolio of pharmaceutical products under their
293 control.

294 Global, multi-industry standards aid in industries being able to manage data on the wide
295 variety of products that they are responsible for. The GS1 standard for serial number is
296 based on a system of standards that have been developed globally and with multi-industry
297 input. The GS1 General Specifications defines a Serial Number as being a variable length,
298 up to 20 characters, alpha-numeric field using Application Identifier 21 or AI(21). GS1
299 conducted a study that determined that AI(21) is sufficient for the needs of the
300 pharmaceutical industry. We believe this gives all manufacturers enough flexibility to
301 identify their pharmaceutical products in a manner that best suits the particular needs of
302 their customers, packaging limitations and products.

303 We recommend that the FDA allow the U.S. pharmaceutical supply chain to make full use of
304 the GS1 Application Identifier for Serial Number. We believe this would result in
305 manufacturers making the correct choice for their pharmaceutical products and allow other
306 supply chain partners and software vendors to make use of a global standard to their benefit.

307 **FDA Question 3: Blood and Blood Components**

308 *Blood and blood components currently use either the ISBT 128*
309 *standards or Codabar for product package identification. In addition,*
310 *hematopoietic stem cells derived from peripheral and cord blood use*
311 *the ISBT 128 standard for product package identification. Please*
312 *comment on whether these standards should be designated as the SNI*
313 *for such products.*

314 Responding to the healthcare community's need to manage products from multiple
315 industries; GS1 and the ICCBBA (managers of the ISBT 128 standard) have initiated a joint
316 working group to explore the interoperability between the GS1 and ICCBBA systems of
317 standards. Also, it is our understanding that organizations within the U.S. blood supply
318 chain have either migrated from the Codabar standard to the ISBT 128 system or have
319 committed to do so as soon as computer systems can be updated. It should, therefore, be
320 planned that all blood and blood components in the U.S. will be labeled with ISBT 128.

321 GS1 looks forward to the outcome of the joint working group as we would like to see
322 healthcare providers to be able to take advantage of traceability standards for all items they
323 manage. As a consequence we support the use of the ISBT 128 Standard for coding and
324 labeling of blood, cellular therapy, and tissue products.